

The 2009 Influenza Pandemic: An Overview

Updated November 16, 2009

Congressional Research Service

<https://crsreports.congress.gov>

R40554

Summary

On June 11, 2009, in response to the global spread of a new strain of H1N1 influenza (“flu”), the World Health Organization (WHO) declared the outbreak to be an influenza pandemic, the first since 1968. The novel “H1N1 swine flu” was first identified in California in late April. Since then, cases have been reported around the world.

When the outbreak began, U.S. officials adopted a response posture under the overall coordination of the Secretary of Homeland Security. Among other things, officials established a government-wide informational website (<http://www.flu.gov>), released antiviral drugs from the national stockpile, developed new diagnostic tests for the H1N1 virus, and published guidance for the clinical management of patients and the management of community and school outbreaks.

Several federal emergency management authorities have been invoked for the response to the pandemic, including a presidential declaration of a national emergency, and a declaration by the Secretary of Health and Human Services (HHS) of a public health emergency. Among other things, these authorities have allowed federal officials to make certain unapproved drugs available to patients with severe cases of influenza, and to ease certain requirements on hospitals to aid them in caring for surges in the volume of patients.

Federal health officials have purchased millions of doses of H1N1 pandemic flu vaccine, approved through the routine licensing process used for seasonal flu vaccines. A voluntary nationwide vaccination program is underway, largely coordinated by state and local health officials and carried out through public clinics, private health care providers, schools, and others. The Secretary of HHS has implemented waivers of liability and an injury compensation program in the event of unforeseen vaccine safety problems. Allocation schemes were developed to give priority for limited vaccine doses to those in high-risk groups. However, there have been a number of problems associated with shortfalls of actual (versus predicted) vaccine availability, and charges that vaccine would not be available for most of the individuals in designated priority groups until after the peak of pandemic virus transmission had passed. Some Members of Congress and others have questioned the adequacy of federal activities to improve the capacity for and timeliness of flu vaccine production.

To address the outbreak, the Obama Administration requested \$2 billion in FY2009 emergency supplemental appropriations, and transfer authority for an additional amount of almost \$7 billion from existing HHS accounts. On June 26, the President signed P.L. 111-32, the Supplemental Appropriations Act, 2009, which provided \$1.9 billion immediately and an additional \$5.8 billion contingent upon a presidential request documenting the need for, and proposed use of, additional funds. The President has subsequently asked for most of the contingent amount. A balance of almost \$1.3 billion remains available.

This report provides a synopsis of key events in the H1N1 pandemic response, followed by information about selected federal emergency management authorities and actions taken by DHS, HHS, and state and local authorities. It then lists congressional hearings held to date; discusses appropriations and funding for pandemic flu preparedness and response activities; summarizes U.S. government pandemic flu planning documents; and lists sources for additional information. An **Appendix** describes the WHO process to determine the phase of an emerging flu pandemic.

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Synopsis

On June 11, 2009, in response to the global spread of a new strain of H1N1 influenza (“flu”), the World Health Organization (WHO) declared the outbreak to be a flu pandemic, the first since 1968. Officials believe the outbreak began in Mexico in March, or perhaps earlier. The novel “H1N1 swine flu” virus was first identified in California in late April. Since then, cases have been reported around the world. The H1N1 pandemic virus is a reassortment of several existing strains of influenza A, subtype H1N1 virus, including strains typically found in pigs, birds, and humans.

Since the H1N1 pandemic virus emerged in the spring, the U.S. Centers for Disease Control and Prevention (CDC) has continued the operation of U.S. seasonal (routine) flu surveillance systems, which are normally suspended during the summer. These systems track trends in rates of illness and hospitalization but are imprecise in their accounting for the total numbers of deaths and hospitalizations due to the pandemic. CDC has published an estimate of these counts, stating that between April and October 17, there were between 14 million and 34 million cases of H1N1 infection, between 63,000 and 153,000 H1N1-related hospitalizations, and between 2,500 and 6,000 H1N1-related deaths in the United States. (See “CDC: Disease Surveillance, and Estimates of Illnesses and Deaths.”)

2009 H1N1 Influenza Pandemic Status as of November 16, 2009

International: World Health Organization (WHO):

(<http://www.who.int/csr/disease/swineflu/en/index.html>)

- WHO declared an influenza pandemic (Phase 6) on June 11. On July 11, WHO asked nations to suspend routine reporting of cases, and stopped publishing case counts, saying they did not accurately reflect pandemic status.
- WHO advises no restriction of regular travel or closure of borders; however, sick individuals are advised to delay travel. Officials report no infection risk from consumption of well-cooked pork products.

United States Government:

(<http://www.flu.gov/>; <http://www.cdc.gov/h1n1flu/>; <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm150305.htm>)

- A Public Health Emergency is in effect under Section 319 of the Public Health Service Act.
- CDC has released to states treatment courses of antiviral drugs, including Tamiflu, Relenza, and the intravenous drug peramivir.
- FDA has issued Emergency Use Authorizations for unapproved uses of Tamiflu and Relenza, use of the unapproved antiviral drug peramivir and unapproved diagnostic tests, and certain uses of protective equipment.
- CDC has issued guidances for the general public; for clinicians and laboratories; regarding pregnant women and other groups; regarding travel; regarding affected schools and communities; and others.
- Congress provided up to \$7.7 billion in emergency supplemental appropriations for FY2009 (P.L. 111-32).
- FDA has approved five vaccines against H1N1 flu, through the routine flu vaccine licensing process.
- Health officials have launched a vaccination campaign. HHS Secretary Sebelius has waived liability associated with the use of pandemic vaccine, and enabled an injury compensation program. Priority groups have been identified.
- The President has declared the pandemic to be a national emergency, allowing waivers of some requirements under Medicare and Medicaid law to help health care facilities manage increased numbers of patients.
- CDC estimates that as of October 17, the pandemic had caused between 14 million and 34 million cases of H1N1 infection, between 63,000 and 153,000 H1N1-related hospitalizations, and between 2,500 and 6,000 H1N1-related deaths in the United States.

The CDC reports that the symptoms and transmission of the novel H1N1 flu from person to person are generally similar to seasonal flu. Laboratory testing of the new strain indicates that the antiviral drugs oseltamivir (Tamiflu) and zanamivir (Relenza) are generally effective in treating illnesses caused by the pandemic strain. In contrast to seasonal flu, the pandemic strain appears to cause serious illness more often among children, and less often among the elderly. However, like seasonal flu, pregnant women and individuals with serious chronic diseases appear to be at greater risk of serious illness from the pandemic strain.

In response to the outbreak in April, Janet Napolitano, Secretary of the Department of Homeland Security (DHS), assumed the role of Principal Federal Official, coordinating federal response efforts. Charles E. Johnson, then the Acting Secretary of Health and Human Services (HHS), declared a public health emergency, which remains in effect. Among other things, this has allowed the Food and Drug Administration (FDA) to issue Emergency Use Authorizations (EUAs), permitting certain unapproved uses of antiviral drugs (such as in very young children) and some types of protective facemasks, the use of unapproved diagnostic tests for the new flu strain, and the use of the unapproved antiviral drug peramivir. HHS has established a government-wide informational website (www.flu.gov) with information for planners, health care providers, and the public. On October 24, President Obama declared the pandemic to be a national emergency, which allowed waivers of some requirements under Medicare and Medicaid law to help health care facilities manage increased numbers of patients. To date, there has not been a presidential declaration regarding the pandemic under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act). The applicability of this Act to infectious disease incidents is unclear. (See “Key Federal Government Authorities and Actions” and **Figure 1**, “Selected Federal Emergency Management Authorities Applicable to the H1N1 Influenza Pandemic.”)

Many U.S. communities closed schools when students were found to be infected with the new flu strain. School closure decisions, made by local officials, were based on initial CDC guidance, which was revised as it became clear that the virus was in wide circulation, and that the illnesses it caused were generally mild. CDC now recommends against routine school closures when small numbers of students are infected, arguing that such closures may do little to reduce the spread of the virus, while placing a considerable burden on the affected community. (See “Pandemic Preparedness and Response in Schools.”)

The U.S. response to the pandemic triggered a slate of plans that were developed, beginning around 2004, to address concerns about the global spread of another novel flu strain, the H5N1 avian flu. (See box below for definitions.) In FY2006 supplemental appropriations, Congress provided \$6.1 billion for pandemic planning across several departments and agencies. These earlier efforts, and others aimed at preparedness for bioterrorism and emerging infections in general, have generally streamlined the response to the H1N1 pandemic. To address the H1N1 outbreak, the Obama Administration requested \$2 billion in FY2009 emergency supplemental appropriations, and transfer authority for an additional amount of almost \$7 billion from existing HHS accounts. On June 26, the President signed P.L. 111-32, which provided \$1.9 billion in FY2009 supplemental appropriations immediately, and an additional \$5.8 billion contingent upon a presidential request documenting the need for additional funds. The President has twice requested portions of the contingent funding. (See “Appropriations and Funding.”)

Influenza Defined

Influenza (“flu”) is a respiratory illness that can be transmitted from person to person. Flu viruses are of two main genetic types: Influenza A and B. Influenza A strains are further identified by two important surface proteins that are responsible for virulence: hemagglutinin (H) and neuraminidase (N).

Seasonal flu circulates each year in the winter in each hemisphere. The dominant flu strains in global circulation change from year to year, but most people have some immunity. Infection can be fatal, however. CDC estimates that there are about 36,000 deaths from seasonal flu each year, on average. Vaccines are made each year based on predictions of the strains that are most likely to circulate in the upcoming flu season.

Avian flu (“bird flu”) is caused by viruses that occur naturally among wild birds, and that may also affect domestic poultry. In 1997, a new H5N1 strain of avian flu emerged in Asia, and has since caused millions of deaths among domestic poultry, and hundreds of deaths in humans. Health officials have been concerned that this strain could cause a human pandemic, and governments around the world have carried out a number of preparedness activities, including vaccine development and stockpiling, and planning for continuity of services.

Swine flu occurs naturally among wild and domestic swine. People do not normally get swine flu, but each year CDC identifies a few isolated cases of human flu that are caused by flu strains typically associated with swine.

Pandemic flu is caused when a novel strain of human flu (i.e., one that spreads from person to person) emerges and causes a global outbreak, or pandemic, of serious illness. Because there is little natural immunity, the disease is often more severe than is typical of seasonal flu.

(Adapted from HHS, “Flu Terms Defined,” <http://www.pandemicflu.gov>. For more information about pandemic flu, see “Understanding Pandemic Influenza” in CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*.)

A voluntary national pandemic vaccination campaign is underway. In June, HHS Secretary Kathleen Sebelius issued a declaration waiving liability and enabling a compensation program in the event that injuries result from use of pandemic vaccine. CDC has developed recommendations for groups of individuals who should be given priority for vaccine when it is available in limited amounts. Costs associated with the vaccination program are being funded through both public and private sources. Vaccine is being provided to states as it becomes available, according to states’ populations. Vaccine delivery is carried out by a CDC contractor. Decisions regarding vaccine distribution to health care providers, clinics, schools, and other vaccination sites are the responsibility of state and local governments. There have been a number of problems associated with shortfalls of actual (versus predicted) vaccine availability, and charges that vaccine would not be available for most of the individuals in designated priority groups until after the peak of pandemic virus transmission had passed. (See “Vaccines and Pandemic Influenza.”)

This report provides information about selected federal emergency management authorities and actions taken by DHS and HHS, and actions taken by state and local authorities, in response to the pandemic. It then lists congressional hearings held to date; provides information about appropriations and funding for pandemic flu preparedness and response activities; summarizes U.S. government pandemic flu planning documents; and lists sources for additional information about the pandemic. An **Appendix** describes the WHO process to determine the phase of a threatened or emerging flu pandemic, and touches on several related issues. All dates in this report refer to 2009 unless otherwise specified. This report will be continually updated to reflect unfolding events.

Key Federal Government Authorities and Actions

Government-wide Pandemic Preparedness and Response

Leadership and Coordination

Under current law, the Secretary of Homeland Security leads all federal incident response activities, while the Secretary of HHS leads all federal public health and medical incident response activities under the overall leadership of the Secretary of Homeland Security.¹ The Government Accountability Office (GAO) has noted, in the context of pandemic flu planning, that “these federal leadership roles involve shared responsibilities between [HHS] and [DHS], and it is not clear how these would work in practice.” GAO recommended that HHS and DHS conduct training and exercises to ensure that federal leadership roles are clearly defined and understood. As recently as July 2009, GAO testified that although some recommended exercises had been undertaken, it was unclear whether they rigorously tested federal leadership roles in a pandemic. GAO also recommended, among other things, that federal pandemic plans published in 2006 be updated.² In July, DHS Deputy Secretary Jane Holl Lute testified that an implementation plan for response to the current pandemic was being finalized under the leadership of the National Security Council.³

In August, the President’s Council of Advisors on Science and Technology (PCAST) released a report assessing preparations for a possible resurgence of H1N1 flu and recommending additional actions.⁴ PCAST also noted the potential ambiguity in the leadership roles of DHS and HHS, and recommended that the Homeland Security Advisor⁵ be given primary responsibility for decision making during the pandemic response, saying:

The Working Group has some concerns, based on conversations with representatives of the various agencies involved, that decision-making authorities and processes may not be completely clear in all cases. Primary Federal responsibilities for response to an epidemic are lodged in two departments ([HHS] and DHS), with significant involvement of others (Education, Defense, State, Agriculture, Labor), and coordination by White House staff. While the National Strategy for Pandemic Influenza Implementation Plan provides a comprehensive list of assignments for a multitude of offices, agencies, and departments involved in the Federal planning process, the large number of tasks and responsible units

¹ See CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister.

² See, for example, U.S. Government Accountability Office, *Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to Be Addressed*, GAO-09-909T, July 29, 2009, pp. 6-7, <http://www.gao.gov>.

³ Comments of DHS Deputy Secretary Jane Holl Lute, U.S. Congress, House Committee on Homeland Security, *Beyond Readiness: An Examination of the Current Status and Future Outlook of the National Response to Pandemic Influenza*, 111th Cong., 1st sess., July 29, 2009.

⁴ Executive Office of the President, President’s Council of Advisors on Science and Technology, *Report to the President on U.S. Preparations for 2009-H1N1 Influenza*, August 7, 2009, press release and link to full report at http://www.whitehouse.gov/the_press_office/Presidents-Council-of-Advisors-on-Science-and-Technology-PCAST-releases-report-assessing-H1N1-preparations/ (hereafter referred to as PCAST report).

⁵ This designation presumably refers to John Brennan, who serves as Assistant to the President for Homeland Security and Counterterrorism. For more information on the organization of the Homeland Security Council and its staff under the Obama Administration, see The White House, Office of the Press Secretary, “Statement by the President on the White House Organization for Homeland Security and Counterterrorism,” press release, May 26, 2009, http://www.whitehouse.gov/briefing_room/PressReleases/.

tends to obscure the primary seat of responsibility.... The Working Group believes it would be valuable to clarify these matters before events accelerate in September and assign to the Homeland Security Advisor the responsibility for ensuring that all of the important decisions are made in a timely fashion and with appropriate consultation with the President.⁶

Declaration of a National Emergency

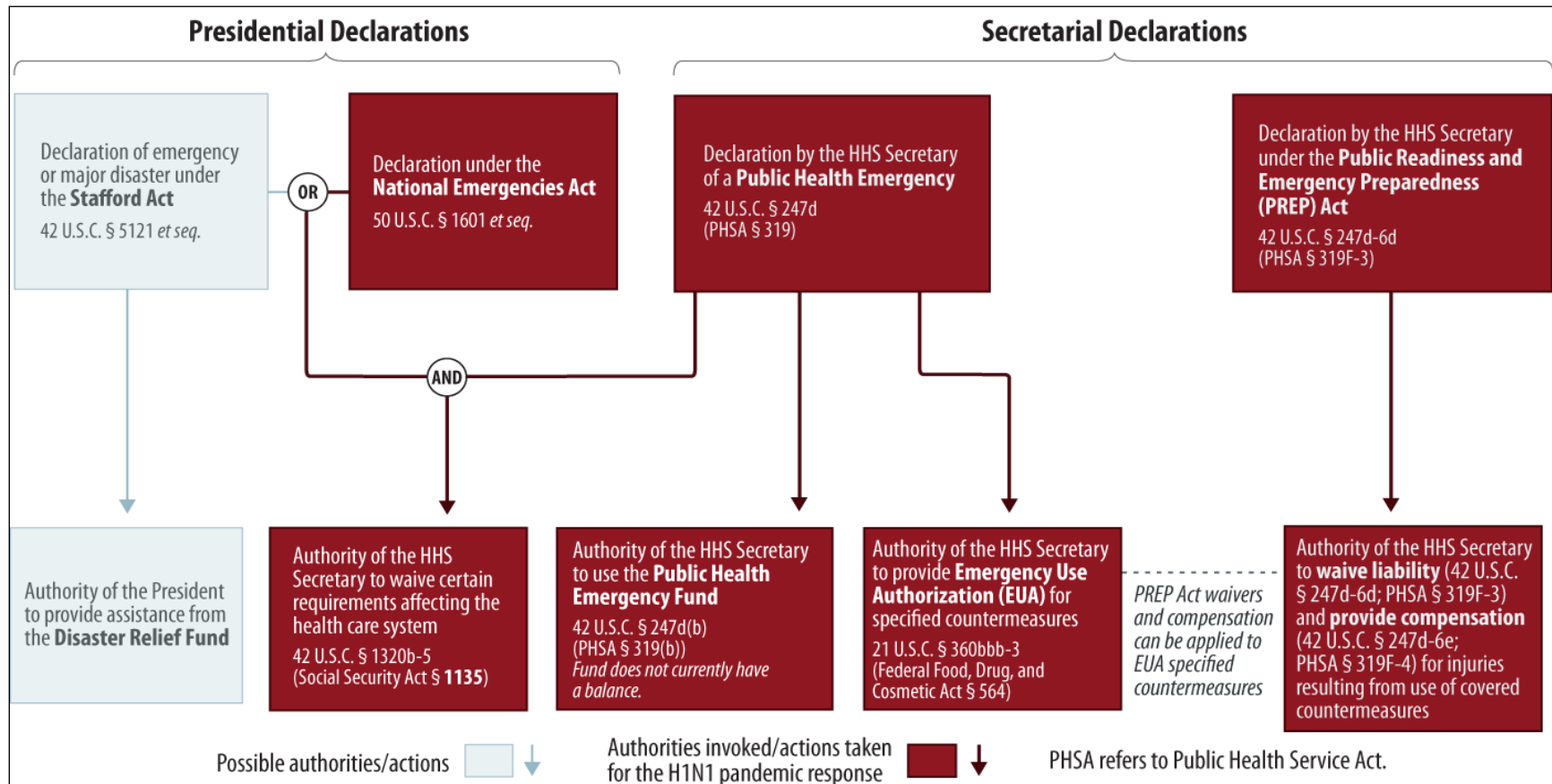
On October 23, President Obama declared an emergency, pursuant to the National Emergencies Act, with respect to the H1N1 pandemic. Specifically, the President proclaimed that because “the rapid increase in illness across the nation may overburden health care resources and ... the temporary waiver of certain standard Federal requirements may be warranted in order to enable U.S. health care facilities to implement emergency operations plans, the 2009 H1N1 influenza pandemic in the United States constitutes a national emergency.”⁷

The National Emergencies Act provides the President with broad authority to waive statutory requirements, or to invoke other authorities, limited to those he specifies in an emergency declaration. In this case, the declaration was limited to a set of requirements under the Social Security Act, enumerated in Section 1135 of that Act, that may be waived if there are in effect *concurrently* a declaration of public health emergency *and* a presidential declaration under *either* the National Emergencies Act *or* the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act). The National Emergencies Act, the “Section 1135” waiver authority, and other federal emergency management authorities that have been invoked or could be invoked for the response to the flu pandemic are depicted in **Figure 1**. Because a public health emergency declaration was already in effect, the declaration under the National Emergencies Act provided the authority for the Secretary of HHS to waive the Social Security Act requirements in order to make it easier for health care facilities to manage surges in patient volume during the pandemic. The Stafford Act has not been invoked for the response to the H1N1 pandemic. Its possible applicability to this incident is discussed in a subsequent section of this report, “Applicability of the Stafford Act.” Also, the “Section 1135” waivers are discussed in more detail in a subsequent section, “Waivers or Modifications Under Section 1135 of the Social Security Act.”

⁶ PCAST report, p. 32.

⁷ The text of the President’s Proclamation, “Declaration of a National Emergency with Respect to the 2009 H1N1 Influenza Pandemic,” October 23, 2009, and related information are available at <http://www.flu.gov/professional/federal/h1n1emergency10242009.html>. See also CRS Report 98-505, *National Emergency Powers*, by L. Elaine Halchin.

Figure 1. Selected Federal Emergency Management Authorities Applicable to the H1N1 Influenza Pandemic



Source: Developed by Congressional Research Service.

Notes: (1) This figure depicts selected authorities that were invoked or could be invoked for the response to the H1N1 flu pandemic, and does not necessarily reflect all available authorities or actions. For example, the National Emergencies Act confers broad authority to the President to waive statutory requirements, or to invoke other authorities, as specified in the declaration of emergency. In this case the declaration was limited to authorities in Section 1135 of the Social Security Act. Similarly, presidential declarations under the Stafford Act may enable authorities, such as certain administrative waivers, in addition to the authority to use the Disaster Relief Fund. (2) The authority for Emergency Use Authorization of specified countermeasures, which was triggered for the H1N1 pandemic by the HHS Secretary's declaration of a public health emergency, can alternatively be triggered by a declaration of a domestic emergency by the Secretary of Homeland Security, or a declaration of a military emergency by the Secretary of Defense. [21 U.S.C. § 360bbb-3(b)]

Department of Homeland Security (DHS)

Leadership Designation

On April 27, Janet Napolitano, Secretary of the Department of Homeland Security (DHS), stated in a press briefing that she was serving as the coordinator of the federal response to the flu outbreak, having assumed the role of Principal Federal Official (PFO).⁸ According to the National Response Framework (NRF), which guides a coordinated federal response to disasters and emergencies in general, the Secretary of Homeland Security leads federal incident response.⁹

Applicability of the Stafford Act

As of November 16, the Stafford Act has not been invoked for the response to the H1N1 pandemic. The Act authorizes federal assistance to public and private not-for-profit entities affected by catastrophes, upon a presidential declaration. Two levels of declaration may be made, based on the scope and severity of an incident: a declaration of *emergency*, which provides a lower level of assistance, and a declaration of *major disaster*, which provides a higher level. The Stafford Act is administered by the Federal Emergency Management Agency (FEMA), which can draw from a Disaster Relief Fund to provide assistance for activities that are eligible under the Act.¹⁰

Major disaster declarations under the Stafford Act have historically involved common meteorological or geological disasters, wildfires, and terrorist acts such as bombings. The applicability of major disaster assistance to infectious disease threats—whether natural (e.g., a flu pandemic) or intentional (bioterrorism)—has been a matter of debate. Historically, major disaster assistance has been tailored to address disaster consequences such as the destruction of infrastructure or the displacement of victims, neither of which is a likely consequence of infectious disease outbreaks.

A legal analysis by CRS concluded that emergency assistance under the Stafford Act could be provided by the President in the event of a flu pandemic, but also noted that whether major disaster assistance would be authorized is not clear. There is no precedent for a major disaster declaration in response to an infectious disease threat. Furthermore, the legislative history of the Stafford Act suggests that this issue was not addressed by Congress when it drafted the current definition of a major disaster, and neither inclusion nor exclusion of flu pandemics from major disaster assistance is required as a matter of statutory construction.¹¹

In the *National Strategy for Pandemic Influenza: Implementation Plan*, the George W. Bush Administration assumed that the President's authority to declare a major disaster pursuant to the

⁸ Department of Homeland Security, *Remarks by Secretary Napolitano at Media Briefing on H1N1 Flu Outbreak*, April 27, 2009, <http://www.dhs.gov/ynews/>.

⁹ CRS Report RL34758, *The National Response Framework: Overview and Possible Issues for Congress*, by Bruce R. Lindsay. The PFO position has been controversial, however, because it may conflict with the role of the Federal Coordinating Officer (FCO), a leadership position established in the Robert T. Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act).

¹⁰ CRS Report RL33053, *Federal Stafford Act Disaster Assistance: Presidential Declarations, Eligible Activities, and Funding*, by Keith Bea; and CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister.

¹¹ CRS Report RL34724, *Would an Influenza Pandemic Qualify as a Major Disaster Under the Stafford Act?*, by Edward C. Liu.

Stafford Act could be applied to a flu pandemic.¹² In 2007, FEMA issued a Disaster Assistance Policy regarding Stafford Act assistance that may be provided during a flu pandemic, which includes costs associated with emergency medical care when provided by an eligible entity (generally, a public or non-profit private entity).¹³

In July, DHS Secretary Janet Napolitano suggested that she did not plan to invoke the Stafford Act for the pandemic response.¹⁴ However, DHS Deputy Secretary Jane Holl Lute has testified that the Stafford Act may be invoked for the pandemic response under certain circumstances, and that DHS has planned accordingly.¹⁵ In information provided by HHS regarding the effects of the presidential declaration of national emergency on October 23, it is suggested that state governors may request that the President make a declaration under the Stafford Act in order to provide assistance if state and local resources become insufficient for the pandemic response.¹⁶ A FEMA fact sheet was referenced in order to assist states in assessing impacts and evaluating the need for federal assistance under the Stafford Act.¹⁷ The Stafford Act and other federal emergency management authorities that have been invoked or could be invoked for the response to the H1N1 flu pandemic are depicted in **Figure 1**.

Customs and Border Protection (CBP) Activities

When the H1N1 flu outbreak began in the United States, Customs and Border Protection (CBP), in DHS, reported monitoring incoming travelers at ports of entry (typically a visual inspection for possible symptoms), providing information about disease control measures, and referring symptomatic persons to a CDC quarantine station¹⁸ or a local public health official for evaluation. According to DHS, “There are no border restrictions in effect. U.S. Customs and Border Protection continues to monitor the health status of incoming visitors at our land, sea and air ports watching out for illness as part of their standard operating procedure.”¹⁹

Administration officials resisted calls for more aggressive measures such as closing the U.S.-Mexico border. WHO and CDC officials commented that scientific evidence does not support closure of a border to travelers as an effective means of controlling the spread of influenza.²⁰ Also, as a matter of law, U.S. citizens cannot be barred from entering the United States, so any

¹² Homeland Security Council, *National Strategy for Pandemic Influenza: Implementation Plan*, May 2006, Appendix C, “Authorities and References,” p. 212.

¹³ FEMA, “Emergency Assistance for Human Influenza Pandemic,” Disaster Assistance Policy 9523.17, March 31, 2007, at <http://www.fema.gov/pdf/government/grant/pa/policy.pdf>.

¹⁴ Kevin Robillard, “Officials Say Swine Flu Vaccine is Coming,” *CQ Homeland Security*, July 9, 2009.

¹⁵ Comments of DHS Deputy Secretary Jane Holl Lute, U.S. Congress, House Committee on Homeland Security, *Beyond Readiness: An Examination of the Current Status and Future Outlook of the National Response to Pandemic Influenza*, 111th Cong., 1st sess., July 29, 2009.

¹⁶ HHS, “October 24, 2009—President Obama Signs Emergency Declaration for H1N1 Flu,” in particular the answer to the questions “... How does the President’s National Emergency declaration under the National Emergencies Act differ from a Stafford Act declaration? How does the request process for assistance under the Stafford Act differ from the request process for 1135 waivers?,” <http://www.flu.gov/professional/federal/h1n1emergency10242009.html>.

¹⁷ FEMA, “Disaster Assistance Fact Sheet 9580.106: Pandemic Influenza,” October 22, 2009, http://www.fema.gov/pdf/emergency/pandemic_influenza_fact_sheet.pdf.

¹⁸ CDC, “Quarantine Stations,” http://www.cdc.gov/ncidod/dq/quarantine_stations.htm.

¹⁹ DHS, “Department Response to H1N1 (Swine) Flu,” July 24, 2009, <http://www.dhs.gov/files/programs/swine-flu.shtm>.

²⁰ Donald G. McNeil, “Containing Flu Is Not Feasible, Specialists Say,” *The New York Times*, April 29, 2009. See also WHO, *No Rationale for Travel Restrictions*, May 1, 2009, http://www.who.int/csr/disease/swineflu/guidance/public_health/travel_advice/en/index.html.

border closure could only exclude aliens.²¹ Finally, any such measures would likely be resource-intensive, involving considerable disruption of trade and other economic interests.²²

Department of Health and Human Services (HHS)

Determination of a Public Health Emergency

On April 26, Charles E. Johnson, then the Acting HHS Secretary, declared a public health emergency pursuant to Section 319 of the Public Health Service Act (PHSA).²³ This enabled FDA to implement an authority in the Federal Food, Drug, and Cosmetic Act (FFDCA) allowing for the emergency use of unapproved medical treatments and tests, under specified conditions, if needed during an incident. (See the subsequent section “FDA: Emergency Use Authorizations.”) In addition, while a public health emergency declaration is in effect, the HHS Secretary (or Acting Secretary) is authorized to draw funds for response to the situation from a Public Health Emergency Fund. However, this fund has not had a balance since the 1990s, and hence the declaration did not provide access to this (or any other) emergency funding mechanism. (For more information, see the “Public Health Emergency Funding Mechanisms” section of this report.) The public health emergency determination, which would have expired after 90 days, was renewed by HHS Secretary Kathleen Sebelius on July 24 and again on October 1.²⁴

The public health emergency authority and other federal emergency management authorities that have been invoked or could be invoked for the response to the H1N1 flu pandemic are depicted in **Figure 1**.

Waivers or Modifications Under Section 1135 of the Social Security Act

When there are in effect *concurrently* a declaration of public health emergency *and* a presidential declaration under *either* the National Emergencies Act *or* the Stafford Act, the Secretary of HHS may waive or modify a number of administrative requirements of the Social Security Act and certain health information privacy provisions (as enumerated in Section 1135 of that Act) to streamline the delivery of health care services by facilities facing surges in patient volume.²⁵ These “1135 waivers” principally involve requirements for reimbursement through the Medicare and Medicaid programs, requirements that most health care facilities in the United States choose to meet.

As noted earlier, on October 23, President Obama declared a national emergency pursuant to the National Emergencies Act. (See the “Declaration of a National Emergency” section of this

²¹ See “Closing the Border” in CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.

²² See “Port of Entry Policies and Procedures” in CRS Report R40570, *Immigration Policies and Issues on Health-Related Grounds for Exclusion*, by Chad C. Haddal and Ruth Ellen Wasem.

²³ 42 U.S.C. § 247d. See HHS, “HHS Declares Public Health Emergency for Swine Flu,” press release, April 26, 2009, <http://www.hhs.gov/news>. More information about this authority is available in CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones; and CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister.

²⁴ HHS, “Renewal of Determination that a Public Health Emergency Exists,” July 24, 2009, <http://www.flu.gov/professional/federal/h1n1emergency072409.html>; and October 1, 2009, <http://www.flu.gov/professional/federal/h1n1emergency100109.html>.

²⁵ See “Section 1135 Waivers or Modifications” in CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.

report.) Specifically, the President proclaimed that because “the rapid increase in illness across the nation may overburden health care resources and ... the temporary waiver of certain standard Federal requirements may be warranted in order to enable U.S. health care facilities to implement emergency operations plans, the 2009 H1N1 influenza pandemic in the United States constitutes a national emergency.” The President further authorized the Secretary of HHS to “exercise the authority under section 1135 of the Social Security Act to temporarily waive or modify certain requirements of the Medicare, Medicaid, and State Children’s Health Insurance programs and of the Health Insurance Portability and Accountability Act [HIPAA] Privacy Rule throughout the duration of the public health emergency declared in response to the 2009 H1N1 influenza pandemic.” As noted earlier, a declaration of public health emergency, pursuant to Section 319 of the PHSA, was already in effect.

Section 1135 of the Social Security Act was enacted in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188). Under this provision, the Secretary may, among other things, waive sanctions under the Emergency Medical Treatment and Active Labor Act (EMTALA) for certain transfers or redirections of patients away from hospital emergency rooms, allowing hospitals to perform triage and direct patients with flu symptoms to alternate facilities set up for that purpose.²⁶ The Secretary may also waive sanctions and penalties for violations of the HIPAA Privacy Rule in order to facilitate medical recordkeeping when such alternate facilities are used.²⁷ On October 27, the Secretary of HHS implemented the 1135 waivers, which are administered by the HHS Centers for Medicare and Medicaid Services (CMS).²⁸

Waivers under Section 1135 may be applied by the Secretary to any geographic emergency area subject to the concurrent declarations.²⁹ Waivers have been implemented several times in recent years, beginning with the response to Hurricane Katrina in 2005, pursuant to concurrent public health emergency and Stafford Act declarations. The H1N1 pandemic is the first instance in which the National Emergencies Act, rather than the Stafford Act, was used to enable the 1135 waivers. The “Section 1135” waiver authority and other federal emergency management authorities that have been invoked or could be invoked for the response to the H1N1 flu pandemic are depicted in **Figure 1**.

FDA: Emergency Use Authorizations

If an emerging defense, national security, or public health threat is identified for which no licensed or approved medical product exists, the FDCA authorizes the FDA Commissioner, under certain conditions, to issue an Emergency Use Authorization (EUA) so that unapproved but potentially helpful countermeasures can be used to protect the public health.³⁰ Pursuant to

²⁶ 42 U.S.C. § 1320b-5(b)(3). During a flu pandemic, patients can be relocated pursuant to a state’s pandemic preparedness plan, if one exists. 42 U.S.C. § 1320b-5(b)(3)(B)(ii). For more information on EMTALA’s requirements, see CRS Report RS22738, *EMTALA: Access to Emergency Medical Care*, by Edward C. Liu.

²⁷ 42 U.S.C. § 1320b-5(b)(7).

²⁸ The waivers and related information are available at CMS “H1N1 Overview,” <http://www.cms.hhs.gov/H1N1/>.

²⁹ 42 U.S.C. § 1320b-5(b). When the 1135 waivers are available pursuant to a Stafford Act declaration, that declaration typically specifies the counties or other geographic areas in which emergency authorities are in effect. The determinations of both public health emergency and national emergency for the H1N1 pandemic apply nationwide.

³⁰ See CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones. See also FDA, *Guidance: Emergency Use Authorization of Medical Products*, July 2007, <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm>; and FDA/CDC, online course on Emergency Use Authorization, 2009, <http://www.bt.cdc.gov/training/eua/index.html>.

authority provided by the public health emergency determination under Section 319 of the PHSA, FDA has issued EUAs to allow emergency use of (1) the antiviral drugs oseltamivir (Tamiflu), zanamivir (Relenza), and peramivir for the treatment or prophylaxis of influenza; (2) disposable respirators for use by the general public; and (3) unapproved diagnostic tests for the new flu strain.³¹ Although Tamiflu and Relenza are already approved for use in the United States, the EUAs support federal recommendations to use them in ways not explicitly approved on the product label, such as the use of a product in young children, or beyond a certain duration of a patient's symptoms. Peramivir is an unapproved antiviral drug that can be given intravenously to seriously ill patients (such as patients on ventilators) who are unable to take the oral Tamiflu or inhaled Relenza preparations.

The EUA authority could have been invoked for a pandemic flu vaccine if one had been developed using approaches that are not used in currently licensed products, such as the addition to the vaccine of additives called adjuvants to enhance the immune response. At this time, however, the U.S. government has not purchased H1N1 pandemic vaccines containing adjuvants. All of the government-purchased vaccines have been approved through the routine licensing process used for seasonal flu vaccines. (See the "Pandemic Vaccine Development, Procurement, Production, and Licensing" section of this report.) The Emergency Use Authorization and other federal emergency management authorities that have been invoked or could be invoked for the response to the H1N1 flu pandemic are depicted in **Figure 1**.

CDC: Disease Surveillance, and Estimates of Illnesses and Deaths

Because illnesses with the novel H1N1 flu have generally been mild, health officials note that the disease may be substantially underreported. Also, health officials in many U.S. states and cities have stopped running confirmatory tests on suspected cases of H1N1 flu, feeling that better use of epidemiology and laboratory resources can be made by monitoring disease spread to new areas, rather than repeatedly confirming its presence in an affected area.³²

To get a clearer picture of the spread of H1N1 influenza in the United States, CDC has continued using its multi-layered surveillance system for seasonal flu (which is normally suspended each year in the spring), to which it has added an additional surveillance component to better track the pandemic. (See box below.) On August 30, CDC began accepting reports from states of all influenza- and pneumonia-associated hospitalizations and deaths for the 2009-2010 season. This component tracks both laboratory-confirmed cases of influenza and "syndromic" reports (i.e., cases coded as having pneumonia or influenza whether or not they were laboratory-confirmed as having influenza). Reporting only laboratory-confirmed cases underestimates the burden of illness due to influenza. (Even when testing is done, the test methods have a significant false-negative rate, meaning that the test is negative even though the patient is infected.) In contrast, syndromic reporting captures some cases of pneumonia that are due to causes other than influenza. As CDC notes, although each measure is imperfect, tracking each one nonetheless provides useful information about trends in the spread of the pandemic, and the burdens experienced by the health care system in responding to it.

³¹ Information is available at FDA, "Emergency Use Authorizations Questions and Answers," <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm153297.htm>; and "Influenza (Flu) Antiviral Drugs and Related Information," <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm>.

³² This approach should not affect medical care. Clinicians are advised to provide care, including treatment with antiviral drugs, based on the severity of a patient's symptoms, the presence of conditions that would place a patient at greater risk of severe infection, and other clinical considerations. It is not necessary that H1N1 flu be confirmed in order for appropriate treatment to be provided.

CDC's Influenza Surveillance Activities

Regular surveillance components used during each annual flu season:

- Viral surveillance, which monitors the percentage of specimens tested for flu that are positive; the types and subtypes of flu viruses circulating; resistance to antiviral medications; and the emergence of new flu strains.
- Selected physician surveillance for influenza-like illness (ILI), which monitors the percentage of visits for symptoms that could be the flu.
- Hospitalization surveillance, which tracks numbers of hospitalizations with laboratory-confirmed flu infections among adults and children.
- Summary of the geographic spread of flu, which tracks the number of states affected by flu, and the degree to which they are affected.
- Deaths from 122 cities that report the total number of deaths and the percentage of those that are coded as influenza or pneumonia.
- The number of laboratory-confirmed deaths from flu among children.

Added surveillance component for the H1N1 flu pandemic:

- Reports by states of either laboratory-confirmed hospitalizations and deaths from flu, or syndromic cases, i.e. cases of presumed influenza and/or pneumonia based on ICD-9 coded hospitalizations or death reports.

Source: Adapted from CDC, "Reporting of Influenza and Pneumonia-Associated Hospitalizations and Deaths for the 2009-2010 Season," September 11, 2009, <http://www.cdc.gov/h1n1flu/reportingqa.htm#surveillancesystems>.

According to CDC, "Routine seasonal surveillance does not count individual flu cases, hospitalizations or deaths (except for pediatric influenza deaths) but instead monitors activity levels and trends and virus characteristics through a nationwide surveillance system."³³ Except for pediatric deaths, the surveillance mechanisms currently available do not provide health officials with an accurate count of deaths attributable to the pandemic. Instead, officials derive estimates from a number of available sources of information, and these estimates are generally considered to reflect mortality more accurately than do "case counts." On November 12, CDC published a comprehensive estimate of the burden of illness caused by the H1N1 pandemic in the United States, stating that between April, when the novel flu strain was first identified, and October 17, there were between 14 million and 34 million cases of H1N1 infection; between 63,000 and 153,000 H1N1-related hospitalizations; and between 2,500 and 6,000 H1N1-related deaths in the United States.³⁴ CDC says it plans to update these estimates every three to four weeks.

CDC's surveillance systems showed that during the week ending November 7, 2009, all of the typed flu viruses reported nationwide were the H1N1 pandemic strain. Thirty-five influenza-associated pediatric deaths were reported, the highest weekly total since the pandemic began. Almost all of the flu viruses tested were sensitive to the antiviral drug Tamiflu. Forty-six states reported widespread influenza activity. Indicators in some regions of the country showed evidence of increasing transmission of the virus, while indicators in some other regions showed declines from previous weeks.³⁵

³³ CDC, "Reporting of Influenza and Pneumonia-Associated Hospitalizations and Deaths for the 2009-2010 Season," September 11, 2009, <http://www.cdc.gov/h1n1flu/reportingqa.htm#surveillancesystems>.

³⁴ CDC, "CDC Estimates of 2009 H1N1 Influenza Cases, Hospitalizations and Deaths in the United States, April – October 17, 2009," November 12, 2009, http://www.cdc.gov/h1n1flu/estimates_2009_h1n1.htm.

³⁵ Information in this section is drawn from CDC, "FluView," <http://www.cdc.gov/flu/weekly/>.

Vaccines and Pandemic Influenza

The 2009 H1N1 Pandemic Vaccine Program

In September, the FDA licensed four vaccines against the H1N1 pandemic flu strain. (A fifth vaccine was licensed in November.) As vaccine became available in early October, federal, state, and local health officials began a voluntary nationwide vaccination campaign, which some have said is the most extensive such effort ever undertaken in the United States. This section discusses the production of the H1N1 pandemic vaccines, various activities involved in conducting the pandemic vaccination program, and associated issues.

Overview

Vaccination is considered the best preventive measure against influenza. But, because of continuous changes in the genes of flu viruses, vaccines must be “matched” to strains in circulation to provoke good immunity, and new vaccines must be developed for each year’s flu season.

In the United States, all currently licensed seasonal flu vaccines are produced using a time-consuming process involving specially raised, fertilized hen’s eggs. First, the virus is adapted for mass production and suitability for use in a vaccine. (The adapted virus is called a “seed” virus.) Next, the seed virus is grown in the eggs in large amounts. Next, small amounts of finished vaccine are produced for use in clinical trials. Finally, if trials demonstrate that the vaccine is safe and effective, then finished vaccine is mass produced.³⁶ Production capacity is finite, so vaccine becomes available in batches. To develop vaccine for a typical Northern Hemisphere flu season, three flu strains are selected in January or February of each year (based on strains circulating in the Southern Hemisphere). Vaccine is produced and becomes available over the next six to nine months, typically from September through December of each year, before the peak of each flu season. Adapting and growing the virus can take variable amounts of time, and different flu strains “behave” differently during this process. In the best case, all of the steps described above take at least four months. More typically, at least six months is required.

Because flu vaccines cannot be produced until the strains they would protect against are in circulation, it was essential, when the H1N1 pandemic was first recognized in late April, to begin development of a vaccine immediately. Although the new flu strain caused illnesses and deaths across the United States from the time it first emerged, it would be months before any vaccine made using current production methods would be available to protect against it.

Recent U.S. pandemic planning efforts have focused on (1) expanding domestic capacity to mass-produce flu vaccine in the near term; (2) developing approaches to speed up and “stretch” existing production capacity, such as through the use of *adjuvants*, vaccine additives that boost the immune response so that a lower virus dose is effective;³⁷ and (3) developing better

³⁶ See, for example, the figure by Sanofi Pasteur (a flu vaccine manufacturer), “A(H1N1) Vaccine Production Process,” May 2009, <http://www.vaccineplace.com/docs/H1N1productionprocess.pdf>. A comparable figure showing the process for production of seasonal flu vaccine is at <http://www.vaccineplace.com/docs/Seasonalfluproductionprocess.pdf>. For additional information about flu vaccine development and manufacturing, see Congressional Budget Office, *U.S. Policy Regarding Pandemic-Influenza Vaccines*, September 2008, <https://www.cbo.gov/ftpdocs/95xx/doc9573/09-15-PandemicFlu.pdf>.

³⁷ For more information about the use of adjuvants, including safety concerns and possible effects on the global supply of pandemic flu vaccine, see Declan Butler, “Regulators Face Tough Flu-jab Choices,” *Nature News*, July 21, 2009, <http://www.nature.com/news/2009/090721/full/460446a.html>.

approaches for flu vaccine production in the future. Although recent progress has been made to improve domestic production capacity, the vaccines developed for use in the United States against the H1N1 pandemic strain use the egg-based process, with its significant lag time.

Pandemic Vaccine Development, Procurement, Production, and Licensing

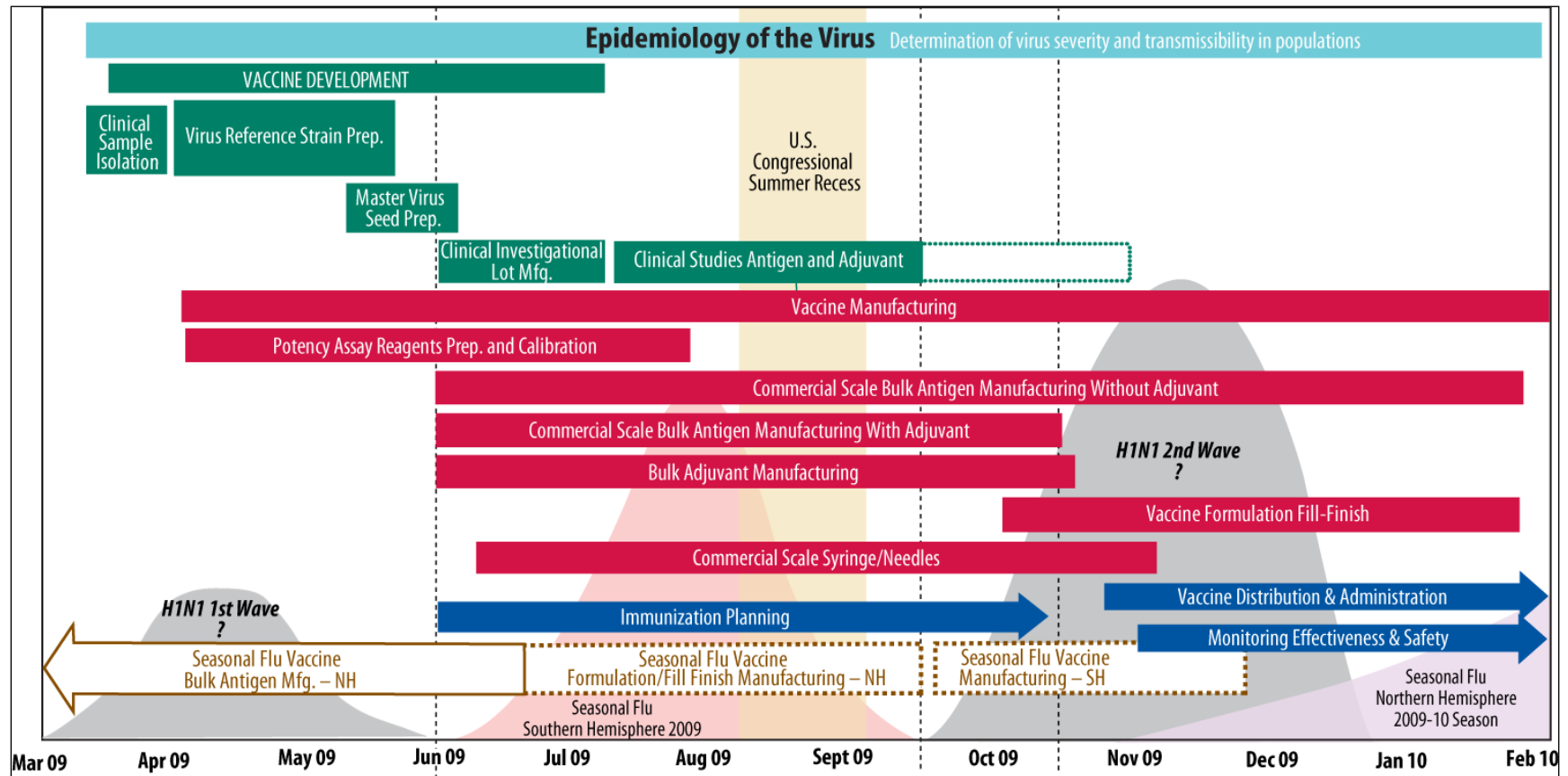
This section discusses influenza vaccine development, procurement, production, and licensing for the H1N1 pandemic. Issues related to improving future influenza vaccine production capacity are discussed in a later section of this report, “Ways to Improve Influenza Vaccine Production in the Future.”

Federal officials have said that there are three key decision points in developing and using pandemic flu vaccines: (1) to develop adapted “seed” viruses and a prototype vaccine(s), and to conduct clinical trials; (2) to purchase and mass-produce large amounts of a promising vaccine; and (3) to administer the vaccine widely, that is, to conduct a mass-vaccination campaign. These decision points are presented in a timeline of the U.S. pandemic flu vaccine strategy in **Figure 2**. The figure also shows that a second wave of heightened transmission of H1N1 flu in the United States in the fall could precede the peak of seasonal flu activity and the initial availability of pandemic vaccine. Finally, the figure shows the overlap between the production of seasonal flu vaccine for the Northern Hemisphere and production of H1N1 pandemic vaccine.

Over the spring and summer, HHS issued purchase orders for H1N1 pandemic vaccine, based on existing contracts with producers of seasonal flu vaccines that are currently licensed in the United States.³⁸ Development and procurement efforts are led by the HHS Biomedical Advanced Research and Development Authority (BARDA), in coordination with the National Institutes of Health (NIH), FDA, CDC, and other HHS agencies.

³⁸ See HHS, “HHS Takes Additional Steps Toward Development of Vaccine for the Novel Influenza A (H1N1),” press release, May 22, 2009; and HHS, “HHS Purchases Additional H1N1 Vaccine Ingredients,” press release, July 13, 2009, (each at <http://www.hhs.gov/news/>). See, also, HHS, Biomedical Advanced Research and Development Authority (BARDA), “H1N1 Vaccines,” <http://www.hhs.gov/aspr/barda/index.html>.

Figure 2. Timeline for H1N1 Pandemic Vaccine Development, Manufacturing, and Possible Distribution and Administration



Source: Adapted by CRS from background material provided for a meeting of the National Biodefense Science Board (administered by HHS) regarding the U.S. 2009 H1N1 vaccine strategy, May 22, 2009, <http://www.hhs.gov/aspr/conferences/nbsb/090522-nbsb-meeting.html>.

The NIH National Institute of Allergy and Infectious Diseases (NIAID) is responsible for coordinating clinical trials to determine safety, effectiveness, and optimum dosing for the H1N1 pandemic vaccine.³⁹ Trials conducted in late summer on healthy adults yielded favorable results. First, the same dose of virus that is used in seasonal flu vaccines was protective when used for the pandemic vaccine. Second, one pandemic vaccine provided protection in adults; a “booster” would not be needed. Third, no serious safety concerns were noted. As a result, large numbers of pandemic vaccines could be produced with existing capacity. Also, adjuvants would not be used, which meant that pandemic vaccines could be evaluated for licensing through the usual process for seasonal flu vaccines; namely, as amendments to the existing product licenses. Emergency Use Authorizations would not be necessary. (See the prior section, “FDA: Emergency Use Authorizations,” for more information about this authority.) H1N1 vaccine clinical trials on children, pregnant women, and individuals with HIV are also underway or have been completed. Finally, NIAID has begun clinical trials on H1N1 vaccines containing adjuvant. Officials have said that although they do not think that adjuvanted vaccine will be needed for the domestic pandemic vaccination program, it could be useful to have the option to use adjuvanted vaccine if the virus mutates to a different form (potentially rendering the non-adjuvanted vaccines less effective). They have also said that research on adjuvants contributes to the knowledge base to improve influenza vaccine production in general.

On September 16, FDA announced that it had approved H1N1 pandemic flu vaccines made by four companies: Sanofi Pasteur Inc., CSL Limited, Novartis Vaccines and Diagnostics Limited, and MedImmune LLC.⁴⁰ On November 10, FDA approved a fifth pandemic vaccine made by ID Biomedical Corporation of Quebec, a subsidiary of GlaxoSmithKline. The Medimmune product is an intranasal vaccine. The other four products are injectable vaccines. The approved uses of each product vary somewhat. In general, for the injectable vaccines, healthy adults should receive one dose, and children aged six months to nine years of age should receive two, in order to raise protective immunity. None of the products is approved for use in infants under six months of age. The approved uses for the intranasal vaccine are more narrow than for the injectable products. In general, the intranasal vaccine is approved for use in healthy individuals aged 2 to 49 years. None of the products contains an adjuvant. The injectable products are available in both multi-dose vials containing a preservative, and in single-dose syringes without a preservative.⁴¹

Vaccine Financing⁴²

Congress provided up to \$7.65 billion in FY2009 supplemental appropriations to HHS for the pandemic response, part of which has been used to support the purchase of vaccine and associated

³⁹ Information in this paragraph is drawn from NIH, National Institute of Allergy and Infectious Diseases (NIAID): “H1N1 Clinical Studies” at <http://www3.niaid.nih.gov/topics/Flu/>; and news releases at <http://www3.niaid.nih.gov/news/newsreleases/>.

⁴⁰ FDA, “Vaccines Approved for H1N1 Influenza Virus,” press release, September 15, 2009, <http://www.fda.gov/NewsEvents/Newsroom>. See also FDA, “Influenza A (H1N1) 2009 Monovalent,” which includes questions and answers and other information about all of the licensed pandemic vaccines, <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm>.

⁴¹ In the United States, seasonal flu vaccine is produced in multi-dose vials containing the preservative thimerosal, and in preservative-free single dose syringes. Thimerosal contains mercury. According to CDC, there is no convincing scientific evidence of harm caused by thimerosal in vaccines, but in 1999, the CDC, other federal agencies, the American Academy of Pediatrics, and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines as a precautionary measure. As is the case for seasonal flu vaccine, a portion of the pandemic vaccine is being produced without preservatives for use in children and pregnant women. See CDC, “Mercury and Vaccines (Thimerosal),” <http://www.cdc.gov/vaccinesafety/updates/thimerosal.htm>.

⁴² Information in this paragraph is drawn from CDC, “Questions and Answers on 2009 H1N1 Vaccine Financing,” October 7, 2009, http://www.cdc.gov/H1N1flu/vaccination/statelocal/vaccine_financing.htm.

costs of planning and carrying out a nationwide vaccination campaign. (See the subsequent section “Emergency Supplemental Appropriations for FY2009.”) There are two types of costs associated with furnishing vaccinations to individuals: the costs of the vaccine and associated supplies, and the costs for administration of the vaccine, which typically include the value of a provider’s time, costs for refrigerated storage and recordkeeping, and related costs.

According to CDC, all pandemic flu vaccines and necessary supplies—syringes, needles, sharps containers, and alcohol swabs—have been purchased by the federal government and are being made available to vaccinators across the country at no cost. In no case may a provider or insurer charge individuals for these costs. Plans for payment of administration costs vary. Medicare, the Department of Veterans Affairs, and many private insurers have said they will cover the costs of administration for seasonal flu vaccine and one or more pandemic vaccines. Private providers (including physicians and chain pharmacies) may charge appropriate fees for the costs of administration if public or private insurance is not available, or they may waive these fees. States are expected to use a portion of the federal funds they received for pandemic planning to support clinics at which individuals who are uninsured can be vaccinated without charge. Also, Federally Qualified Health Centers are expected to provide services, including vaccination for pandemic flu, regardless of ability to pay.

Vaccine Distribution⁴³

Federal officials are working with state and local health officials to implement a “blended” public- and private-sector distribution approach to provide pandemic vaccines to any individuals who want to be vaccinated. During each flu season, much of the vaccine is purchased and delivered through private-sector distributors and providers. For the response to unanticipated threats such as bioterrorism, CDC maintains the Strategic National Stockpile (SNS) of drugs and medical supplies, and provides training and technical assistance to state and local health officials, who are responsible for distribution of stockpile materiel within their jurisdictions. Under the Vaccines for Children program, CDC distributes recommended pediatric vaccines (financed by the Medicaid program) to private providers for administration to eligible low-income children. The blended approach being used for the pandemic vaccination campaign uses portions of each of these mechanisms to make vaccine available to a variety of public- and private-sector providers and clinics. To distribute vaccine as it becomes available, CDC has contracted with McKesson Corporation, the agency’s contractor for distribution under the Vaccines for Children program.⁴⁴

In early October, limited amounts of the approved intranasal H1N1 pandemic vaccine became available and were provided to states according to their populations. Available amounts were less than expected, posing problems for many states and localities, which had planned to conduct or coordinate vaccination clinics based on projected vaccine availability.⁴⁵ In August, CDC reported expecting “... somewhere between 45 million and 52 million doses of vaccine to be available by mid-October. This will be followed by weekly availability of vaccine up to about 195 million

⁴³ Unless otherwise noted, information in this paragraph is drawn from CDC, “H1N1 Flu Vaccination Resources,” <http://www.cdc.gov/h1n1flu/vaccination/>.

⁴⁴ Robert Roos, “States to Designate Providers to Give H1N1 Vaccines,” *CIDRAP News* (Center for Infectious Disease Research and Policy), August 10, 2009, <http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/news/index.html>.

⁴⁵ See for example testimony of Dr. Donald Williamson, Alabama Department of Public Health, and Mr. Rob Fulton, St. Paul Ramsey County, Minnesota, Department of Public Health, at a briefing of the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, November 4, 2009, http://appropriations.house.gov/Subcommittees/sub_lhse.shtml.

doses by the end of the year.”⁴⁶ In mid-October, CDC reported that only 11.4 million doses of the injectable H1N1 vaccine were available.⁴⁷ CDC said that manufacturers were experiencing several problems that affected production volume, including slower than expected growth of the virus in eggs.

Despite high demand for the vaccine, some states appear to have had difficulty getting available vaccine into distribution in their jurisdictions. The distribution plan calls on states to “order” vaccine from their allotments when they are ready to direct how it is to be distributed within the state. HHS publishes daily updates of the total (national) amounts of vaccine *allocated* (i.e., available to states), *ordered* by states, and actually *shipped*, as well as daily updates of the number of vaccines shipped to each state.⁴⁸ Because vaccine is allocated to states according to population, calculating the number of vaccines shipped to each state according to its population should yield similar ratios if the states are similar in their efficiency at ordering and directing the distribution of vaccine within their jurisdictions. However, a news organization has published such an analysis and found considerable variation among the states.⁴⁹

Despite some statements to the contrary, the civilian vaccination program for the H1N1 pandemic is voluntary. There have been no plans at the federal, state, or local level to require that members of the general public be vaccinated. However, requirements have been established by the Department of Defense, and by some states and private health systems, for the vaccination of health care workers. Public health officials recommend that health care workers be vaccinated against influenza (including pandemic flu) not only for their own protection, but also in order to protect patients from infection by their providers, and to prevent levels of absenteeism among providers that could threaten the quality of patient care.⁵⁰

Allocation to Priority Groups⁵¹

CDC advises that anyone who wishes to be vaccinated for seasonal and/or pandemic influenza should seek the vaccine(s) when adequate supplies are available. Certain groups are especially advised to be vaccinated due to their risk of more serious complications from influenza, the risk that they would transmit influenza to others, or both. These groups, identified by the Advisory Committee on Immunization Practices (ACIP, which advises the CDC Director), are

- pregnant women;

⁴⁶ Comments of Dr. Jay Butler, Director of CDC’s H1N1 Vaccine Task Force, transcript of CDC/FDA media briefing, August 21, 2009, <http://www.cdc.gov/media/>.

⁴⁷ Comments of Dr. Anne Schuchat, Director of CDC’s National Center for Immunization and Respiratory Diseases, transcript of CDC media briefing, October 16, 2009, <http://www.cdc.gov/media/>. Although doses of the FluMist intranasal product were also available, that product could not be used in some of the prioritized high-risk groups such as pregnant women and those with chronic diseases.

⁴⁸ HHS, “2009 H1N1 Influenza Vaccine Supply Status,” <http://www.flu.gov/individualfamily/vaccination/supply.html>.

⁴⁹ Rebecca Ruiz, “Behind The H1N1 Vaccine Shortage,” *Forbes*, October 30, 2009, and accompanying chart, “States With the Most and Least H1N1 Vaccine per 1,000 Residents,” updated periodically.

⁵⁰ For information about public health recommendations for flu vaccination among health care workers, see CDC, “2009 H1N1 Vaccination Recommendations,” <http://www.cdc.gov/h1n1flu/vaccination/acip.htm>. For information about the legal basis for mandatory vaccines, see CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones; and CRS Report RS21414, *Mandatory Vaccinations: Precedent and Current Laws*, by Kathleen S. Swendiman.

⁵¹ Unless otherwise noted, information in this paragraph is drawn from CDC, “H1N1 Flu Vaccination Resources,” <http://www.cdc.gov/h1n1flu/vaccination/>.

- persons who live with or provide care for infants aged less than 6 months (e.g., parents, siblings, and daycare providers), because these infants cannot receive the vaccine;
- health-care and emergency medical services personnel;
- persons aged 6 months-24 years; and
- persons aged 25-64 years who have medical conditions that put them at higher risk for influenza-related complications.⁵²

ACIP estimated that the five groups above comprise about 159 million persons in the United States.

Because the H1N1 pandemic vaccine is becoming available in phases, initial demand has exceeded supply. Anticipating this, ACIP also identified a subset of these groups that should be given priority when vaccine supplies are limited. These priority groups are

- pregnant women (as above);
- persons who live with or provide care for infants aged less than 6 months (as above);
- health-care and emergency medical services personnel who have direct contact with patients or infectious material (a subset of the recommended group above);
- children aged 6 months-4 years (only the youngest children); and
- children and adolescents aged 5-18 years who have medical conditions that put them at higher risk for influenza-related complications (only children with medical conditions, versus all persons under age 65 with medical conditions).⁵³

ACIP estimated that this subset of priority groups comprises about 42 million persons in the United States.

Available vaccine may be either the injectable or intranasal formulation. In general, injectable H1N1 vaccine may be given to anyone in one of the priority groups who does not have a specific contraindication (such as an allergy to eggs). However, the intranasal vaccine is not licensed for use in some individuals within the pandemic priority groups. Prioritized individuals who should not receive the intranasal vaccine include pregnant women, children younger than two years of age, individuals of any age who have chronic illnesses, and health care workers who care for severely immunocompromised patients, such as those who have recently undergone bone marrow transplantation. Although federal authorities provide guidance on vaccine allocation, final allocation decisions, and any enforcement of them, is made at the state and local levels.⁵⁴

Adverse Event Monitoring⁵⁵

Although clinical trials were conducted on the approved H1N1 pandemic vaccines and did not show any serious adverse events (i.e., side effects), rare adverse events would not necessarily manifest until a product was widely used. Health officials plan to monitor for any possible

⁵² CDC, "Use of Influenza A (H1N1) 2009 Monovalent Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009," *MMWR*, vol. 58, August 21, 2009, <http://www.cdc.gov/mmwr>.

⁵³ Ibid.

⁵⁴ For a discussion of applicable state activities during the seasonal flu vaccine shortage of 2004-2005, see "Vaccine Rationing" in CRS Report RL32655, *Influenza Vaccine Shortages and Implications*, by Sarah A. Lister and Erin D. Williams.

⁵⁵ Unless otherwise noted, information in this section is drawn from CDC, "Vaccine Safety," http://www.cdc.gov/h1n1flu/vaccination/vaccine_safety.htm.

adverse events among persons who receive the H1N1 pandemic vaccine, using, among other approaches, the existing Vaccine Adverse Event Reporting System (VAERS), a national vaccine safety surveillance program co-sponsored by CDC and FDA. VAERS accepts reports from patients, providers, public health officials, and others through a website and toll-free number.⁵⁶

In 1976, a U.S. vaccination campaign was carried out for a pandemic flu threat that did not materialize (also called “Swine Flu”). However, evidence suggested that among those vaccinated, there may have been an increased risk of a serious and sometimes fatal neurologic side effect, a form of paralysis called Guillain-Barre Syndrome (GBS). The vaccination campaign was called off, and the credibility of public health officials was significantly compromised by the incident.⁵⁷

Liability and Compensation

On June 25, HHS Secretary Kathleen Sebelius issued a declaration under the Public Readiness and Emergency Preparedness Act (PREP Act, Division C of P.L. 109-148) regarding the H1N1 pandemic vaccine.⁵⁸ The PREP Act waives liability and establishes an injury compensation program for the use of certain “covered countermeasures.” The June 25 declaration eliminates liability (with the exception of willful misconduct) for the United States, and for manufacturers, distributors, program planners, persons who prescribe, and employees of any of the above, who administer or dispense an H1N1 pandemic vaccine that qualifies as a “covered countermeasure” under conditions specified by the Secretary in the declaration.⁵⁹ Under the law, claims under state law are preempted. As noted in **Figure 1**, authorities under the PREP Act are independent from other emergency authorities that have been invoked for the response to the H1N1 pandemic.⁶⁰

In addition to the limitation of liability, the PREP Act declaration also establishes a federal program to compensate individuals who are vaccinated for any serious injuries or death that occurs as a result of the H1N1 vaccine, and authority for a fund to pay claims. The compensation program is administered by the HHS Health Resources and Services Administration (HRSA), using the Smallpox Vaccine Injury Compensation Program as an administrative model.⁶¹ The fund, called the Covered Countermeasure Process Fund (CCPF), did not have a balance of funds when the H1N1 pandemic began. However, in providing emergency supplemental funding for pandemic preparedness (P.L. 111-32), Congress authorized the use of an unspecified amount of

⁵⁶ See <http://vaers.hhs.gov/index>.

⁵⁷ For more information, see Richard Neustadt and Harvey Fineberg, *The Swine Flu Affair: Decision-Making on a Slippery Disease* (U.S. Department of Health, Education, and Welfare, 1978), reprinted electronic edition at <http://www.iom.edu/?id=65926>.

⁵⁸ Department of Health and Human Services, Office of the Secretary, “Pandemic Influenza Vaccines—Amendment,” 74 *Federal Register* 30294-30297, June 25, 2009.

⁵⁹ For more information, see CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation*, by Henry Cohen and Vanessa K. Burrows, and “The Public Readiness and Emergency Preparedness Act (PREP Act)” in CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.

⁶⁰ In addition to liability waivers and compensation available for injuries related to the use of H1N1 pandemic vaccine, the PREP Act has also been invoked for the use of pandemic antiviral drugs, diagnostic tests, and protective equipment, as well as for the use of countermeasures for other threats such as anthrax and smallpox. See HRSA, “Countermeasures Injury Compensation Program: Covered Countermeasures,” <http://www.hrsa.gov/countermeasurescomp/countermeasures.htm>.

⁶¹ Health Resources and Services Administration, “Preparedness Countermeasures Injury Compensation,” <http://www.hrsa.gov/countermeasurescomp/default.htm>.

the appropriation for the CCPF.⁶² On July 16, President Obama requested additional contingent funding under the new law, to be used for several activities, including funding for the CCPF.⁶³

Ways to Improve Influenza Vaccine Production in the Future

Strengths and Limitations of Egg-Based Technology

In its 2005 strategy for influenza pandemic preparedness, the George W. Bush Administration set a goal to “establish domestic production capacity to ensure ... [s]ufficient vaccine to vaccinate the entire U.S. population within six months of the emergence of a virus with pandemic potential.”⁶⁴ Because a flu pandemic could emerge at any time, federal officials saw this as a multi-pronged strategy, requiring concurrent investments in the expansion of production capacity using current approaches, and in the development of new approaches.

In January 2009, when announcing federal funding for a new private facility to manufacture cell-based influenza vaccine, an HHS official said that the strategic goal above “... could not be accomplished using the traditional egg-based method of producing flu vaccine.”⁶⁵ Nonetheless, significant federal investments were made to expand production capacity for egg-based vaccine in the event that a flu pandemic arose in the near term. Although concerns were largely driven at the time by the spread of H5N1 avian flu, it was the surprising emergence of H1N1 pandemic flu that proved to be the test of the federal strategy.

Investments to date have had mixed results. The United States has ordered H1N1 pandemic vaccine sufficient to provide 250 million doses, representing substantially greater total capacity than was available only several years ago. Yet the lag time inherent in egg-based vaccine technology is unavoidable, and its effects are stark as the H1N1 pandemic unfolds in a largely unimmunized population. Several observers have suggested that peak nationwide transmission of the virus will have occurred before substantial amounts of vaccine are available.⁶⁶

Some have suggested that even though the lag time to first vaccine availability was unavoidable, there could have been more investment or better planning for the use of egg-based vaccine to avoid the shortage that persists more than a month into the vaccination campaign. For example, some assert that the decision to forgo the use of adjuvants in the pandemic vaccine was made when officials were more optimistic about a timely roll-out of the product, and that more vaccine doses would now be available if adjuvant had been used. However, there are no adjuvant-containing seasonal flu vaccines currently licensed in the United States, so the use of this approach for the pandemic would have required Emergency Use Authorization of the vaccine, which could well have delayed its availability. The use of adjuvants and an emergency licensing process could also have contributed to apprehensions among the public about the vaccine’s safety.

⁶² H.Rept. 111-151, to accompany H.R. 2346, making supplemental appropriations for FY2009, June 12, 2009, pp. 114-115.

⁶³ The White House, Text of a Letter from the President to the Speaker of the House of Representatives, July 16, 2009, http://www.whitehouse.gov/the_press_office/Letter-from-the-President-regarding-H1N1/.

⁶⁴ Homeland Security Council, “National Strategy for Pandemic Influenza,” November, 2005, p. 5, <http://www.flu.gov/professional/federal/index.html#national>.

⁶⁵ HHS, “HHS Awards \$487 Million Contract to Build First U.S. Manufacturing Facility for Cell-Based Influenza Vaccine,” comments of Dr. Robin Robinson, Director of BARDA, press release, January 15, 2009, <http://www.hhs.gov/news/>.

⁶⁶ See for example PCAST Report, p. viii.

Strengths and Limitations of Cell-Based Technology

Other observers assert that greater investment in cell-based (rather than egg-based) vaccine technology could potentially have made that approach viable for the response to the H1N1 pandemic, and that the current vaccination program could have been farther along in that case. In the cell-based approach, the influenza virus is grown in one of a number of types of cells, which are generally easier to manage on the industrial scale than is growth in eggs. The European Medicines Agency (EMA) licensed a cell-based seasonal influenza vaccine, Optaflu, in 2007, and has also licensed a cell-based H1N1 pandemic vaccine, Celvapan.⁶⁷

However, an HHS official, among others, has noted that cell-based approaches to the production of influenza vaccine are not likely to substantially shorten the time to first vaccine availability, compared with egg-based production, because the process still requires growing whole influenza virus in the cells.⁶⁸ Rather, the advantage of cell-based over egg-based production in the near term is one of scalability, or “throughput” (i.e., once virus is grown, vaccines can be finished in large quantities quickly, making hundreds of millions of doses available within weeks rather than months from the time the first batches become available). With egg-based approaches, the dependence on specially produced fertilized eggs limits this scalability. If cell-based approaches had been available for the response to the H1N1 pandemic, it is possible that more vaccine could have been finished by this point, although it still might not have first become available until several months into the pandemic, as was the case with the egg-based vaccines in use.

Recombinant, DNA-Based, and Other Advanced Technologies

Alternative approaches under development for the production of flu vaccine involve technologies that do not require the use of whole viruses (therefore eliminating the need to grow them), but rather focus on producing only those portions (subunits) of the virus that are needed to produce immunity, such as a particular protein in the virus coat. For example, using *recombinant* technology, the genes for the desired virus subunit may be inserted into another microorganism that grows well, such as yeast. The subunit is then replicated by the host microorganism, harvested, purified, and made into a vaccine containing only the subunit, not whole virus. Another recombinant approach places the genes for the desired virus subunit into another virus (called a vector) that introduces the subunit into the body, but does not itself cause disease. More sophisticated approaches to vaccine production involve making *DNA-based* vaccines consisting solely of the viral genes.⁶⁹ The “Holy Grail” for the prevention of influenza is the so-called *universal* influenza vaccine, one that could be administered in childhood to protect against whatever variations of seasonal or pandemic flu arise throughout one’s lifetime.

⁶⁷ The EMA is responsible for the scientific evaluation of applications for authorization for medical products. Authorized products can be marketed in all European Union (EU) and EEA-EFTA states (Iceland, Liechtenstein and Norway). Product information is available at <http://www.emea.europa.eu/>.

⁶⁸ See comments of Anthony Fauci, Director, NIH National Institute of Allergy and Infectious Diseases (NIAID), House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, “Briefing on Federal-State-Local H1N1 Flu Response,” Nov. 4, 2009.

⁶⁹ Each of the approaches discussed here involve growing or replicating virus subunits in cells of one kind or another at some point in the process. These approaches are “cell-based” in that sense. However, when discussing technologies that are currently available for making flu vaccine, the term “cell-based” usually refers to the process for growing whole influenza virus, to distinguish it from the egg-based process.

Federal Efforts to Improve Influenza Vaccine Technology

All U.S.-licensed seasonal and pandemic flu vaccines are made using the whole virus, egg-based approach. As noted earlier, cell-based whole virus influenza vaccines have been licensed in Europe. Recombinant vaccines that have been licensed for use in the United States include those against hepatitis B and human papillomavirus. There has not yet been a DNA-based vaccine licensed for use in humans in the United States or Europe. Each of these approaches to vaccine production, including the production of influenza vaccine, is also applied in licensed or investigational products for veterinary uses in animals.

The NIH provides federal leadership for basic biomedical research on promising vaccine technologies. A search of the NIH ClinicalTrials.gov database yielded a number of clinical trials—in progress or completed—on influenza vaccine prototypes developed using recombinant techniques. The trials range from Phase I—the earliest stage of investigation involving small numbers of human subjects—to Phase III trials involving large numbers of subjects.⁷⁰ In addition, several Phase I trials of DNA-based influenza vaccines were found. In FY2008, NIH reported spending \$204 million on influenza research, including a number of projects specifically involving advanced approaches to influenza vaccine production, and research on other aspects of influenza immunology that are applicable to vaccine development.⁷¹ NIH has also sponsored many clinical trials of vaccines against H1N1 pandemic flu, as well as H5N1 avian and other flu strains, for the purposes of licensing and/or stockpiling these vaccines.⁷² Federal leadership for advanced development of emergency medical countermeasures, including pandemic products, is provided by the Biomedical Advanced Research and Development Authority (BARDA), in HHS. Federal investments in the advanced development of flu vaccine technology came principally from FY2006 emergency supplemental funds for pandemic preparedness,⁷³ and were administered by BARDA. (See the subsequent section “Prior Funding for Pandemic Flu Preparedness.”) HHS has published several reports, as required by Congress, detailing the use of these funds. **Table 1** presents funding amounts for pandemic vaccine development activities, as reported by HHS in January 2009. The focus of this spending has been on expanding egg-based and cell-based vaccine production capacity, as these approaches were clearly viable to make products that could be licensed for use in the United States.

Table 1. FY2006 Supplemental Funding for Pandemic Influenza Vaccine Activities

Obligations, dollars in millions, as of December 31, 2008

Activity	Amount
Egg-based vaccine capacity and purchases ^a	875.7
Retrofit existing facilities for emergency production ^b	121.0
Accelerate cell-based vaccine ^c	1,707.3
Advanced development of antigen-sparing techniques ^d	155.6

⁷⁰ For more information on clinical trials, see NIH, “Understanding Clinical Trials,” <http://clinicaltrials.gov/ct2/info/understand>. FDA generally requires that Phase I through III clinical trials be conducted on medical products to demonstrate safety and effectiveness, in order for a product to be licensed.

⁷¹ NIH, “Estimates of Funding for Various Research, Condition, and Disease Categories,” <http://report.nih.gov/rcdc/categories/>. The listing for influenza spending for FY2008 links to more than 300 funded projects.

⁷² For more information about NIH research on influenza, see <http://www3.niaid.nih.gov/topics/Flu/>; and “NIAID Influenza Research: 2009 Progress Report,” <http://www3.niaid.nih.gov/topics/Flu/PDF/fluResearch09.pdf>.

⁷³ FY2009 emergency supplemental appropriations have been used for the immediate response to the H1N1 pandemic, including the development and procurement of H1N1 vaccine produced using eggs.

Activity	Amount
FDA activities ^e	20
SUBTOTAL, obligations for vaccine activities	2879.5
Unobligated funds for vaccine activities	316.5
TOTAL, allocations for vaccine activities	3,196.0

Source: Prepared by Congressional Research Service from HHS, Assistant Secretary for Resources and Technology, "Report to Congress: Pandemic Influenza Preparedness Spending," Table, pp. 16-17, January 2009, <http://www.hhs.gov/aspr/barda/mcm/panflu/spending.html>.

Notes: Numbers do not add due to rounding.

- Includes funds for contracts with Chiron, GlaxoSmithKline, Novartis, and Sanofi Pasteur for purchase and maintenance of vaccine against H5N1 avian flu.
- Includes funds for contracts with Medimmune and Sanofi Pasteur.
- Includes funds for contracts with Dynport, GlaxoSmithKline, Medimmune, Novartis, and Solvay.
- Includes funds for several contracts to study use of adjuvants.
- Includes funds to expand regulatory capacity, including laboratory expansion and supplies, information technology support, program management, and other activities.

Along with contracts to purchase vaccine from companies developing these products, HHS funds have also been used to construct or retrofit domestic vaccine production facilities. As noted earlier, the national strategic goal for pandemic preparedness was the establishment of sufficient *domestic* flu vaccine production capacity. To this end, HHS funds were provided to Sanofi Pasteur and Medimmune to expand their domestic facilities for egg-based vaccine production.⁷⁴ In addition, HHS has awarded a \$487 million contract to Novartis Vaccines and Diagnostics, Inc., to build a facility in North Carolina to make cell-based seasonal and pandemic flu vaccine.⁷⁵

In April 2009, before the emergence of the H1N1 pandemic flu strain, BARDA announced an upcoming Request for Proposals (RFP) for advanced development of recombinant influenza vaccine products for both seasonal and pandemic use, which would provide federal funding to advance the commercial development of this technology. In its presolicitation notice, HHS said

The timeline for the availability of egg- and cell-based inactivated [i.e., whole virus] pandemic influenza vaccines in the U.S. is estimated at 20-23 weeks post-pandemic onset, which may be towards the end of a first pandemic wave. Recombinant influenza vaccines, on the other hand, may benefit from manufacturing efficiencies, may not be dependent on pandemic influenza virus reference strain availability and/or the production and calibration of potency assay reagents needed for inactivated influenza vaccines. As a result, recombinant influenza vaccines may be available in a shorter time frame of 8 to 12 weeks post-pandemic onset. The effect of vaccination combined with influenza antiviral drugs and community mitigation measures may delay the peak incidence of pandemic influenza disease and reduce mortality and morbidity during a severe pandemic.⁷⁶

⁷⁴ The Sanofi Pasteur product is an injectable vaccine, produced in Swiftwater, PA. The Medimmune product is the intranasal vaccine, produced in Gaithersburg, MD.

⁷⁵ HHS, "HHS Awards \$487 Million Contract to Build First U.S. Manufacturing Facility for Cell-Based Influenza Vaccine," press release, January 15, 2009, <http://www.hhs.gov/news>.

⁷⁶ HHS, BARDA, "Advanced Development of Recombinant Influenza Vaccine Products and Manufacturing Capabilities for Pandemic Preparedness," Solicitation Number HHS-BARDA-09-32, synopsis of presolicitation notice, April 17, 2009, <http://www.fbo.gov>. The solicitation was issued on July 10, 2009.

In response to questions about the RFP above, HHS commented that it intends that successful applicants would pursue approaches applicable to both seasonal and pandemic flu vaccine production. There are obvious advantages to using a tried-and-true approach in an emergency (i.e., basing pandemic flu vaccine production on the approach used to make seasonal flu vaccine). Egg-based seasonal flu vaccine is a safe, inexpensive, and widely accepted product. A possible disadvantage of changing to a different approach is that seasonal flu vaccine could become more costly, at least initially. An HHS official, when asked whether use of cell-based and newer production methods could make seasonal flu vaccine more costly, replied that new technologies were likely to be more expensive initially.⁷⁷ Although there has been little public debate about this, an increase in the cost of seasonal flu vaccine could have consequences for public health efforts to expand the utilization of this product.

Key State and Local Pandemic Response Activities

State Pandemic Preparedness and Response

Since FY2002, all states have received HHS funds to prepare their public health and health care systems for public health threats and emergencies.⁷⁸ Beginning with FY2004, states were required, as a condition of these funds, to develop plans specifically for the response to a flu pandemic. Subsequently, Congress provided \$600 million in FY2006 emergency supplemental appropriations for states to continue their pandemic planning efforts.⁷⁹ When the H1N1 flu outbreak emerged, Congress provided an additional \$350 million in FY2009 emergency supplemental appropriations for state pandemic response.⁸⁰ (See the subsequent section “Emergency Supplemental Appropriations for FY2009.”)

Based on an analysis of state pandemic flu plans available as of July 2006, CRS found the plans to be more robust in their discussion of core public health activities such as disease surveillance and laboratory activities, and less robust in aspects of multi-sector preparedness, such as leadership designation, incident management, certain aspects of health care surge planning, and continuity planning for essential services such as food distribution.⁸¹

In January 2009, HHS and DHS published *Assessment of States’ Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council* (state assessment report), the findings of their comprehensive joint assessment of state pandemic planning through 2008.⁸² This assessment echoed the findings of CRS, saying that preparedness was most advanced with respect to objectives that are exclusively or primarily the responsibility of state public health agencies,

⁷⁷ See comments of Anthony Fauci, Director, NIH National Institute of Allergy and Infectious Diseases (NIAID), House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, “Briefing on Federal-State-Local H1N1 Flu Response,” Nov. 4, 2009.

⁷⁸ Funds are provided to the 50 states, DC, the territories, New York City, Chicago, and Los Angeles County.

⁷⁹ For more information, see the Appendix in CRS Report RL34190, *Pandemic Influenza: An Analysis of State Preparedness and Response Plans*, by Sarah A. Lister and Holly Stockdale; and CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, by Sarah A. Lister.

⁸⁰ Award amounts are available at HHS, “States Eligible to Receive \$350 Million for H1N1, Seasonal Flu Preparedness Efforts,” press release, July 10, 2009, <http://www.hhs.gov/news/>.

⁸¹ CRS Report RL34190, *Pandemic Influenza: An Analysis of State Preparedness and Response Plans*, by Sarah A. Lister and Holly Stockdale.

⁸² HHS and DHS, *Assessment of States’ Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council*, January, 2009, <http://www.pandemicflu.gov/plan/states/index.html>. (Hereafter state assessment report).

namely infectious disease surveillance and clinical laboratory operations; distribution of antiviral drugs and vaccines; mass vaccination; and public communications. In contrast, the assessment found that states were having difficulty planning for surges in health care and emergency medical services, and were especially having difficulty planning for continuity of non-health services, such as continuity of state agency operations; coordination of military support to civil authorities; law enforcement continuity; and ensuring the safety of the food supply.

Thus far, dedicated federal funding to state and local governments for pandemic preparedness has been provided only through HHS grants. Noting the challenges states face in assuring preparedness in non-health sectors, the state assessment report comments, “The [U.S. Government] has provided guidance and technical assistance for many of these activities but generally has not been in a position to award funds to help States develop them in the context of pandemic influenza preparedness.”⁸³

If the pandemic continues to unfold as it has, producing generally mild to moderate illness, the pandemic’s effects on non-health sectors such as transportation and public utilities could be minimal. However, despite the high marks for mass vaccination planning received by most states in the state assessment report, considerable public attention has focused on apparent delays by some states in ordering available vaccine from CDC and promptly distributing it.⁸⁴

Pandemic Preparedness and Response in Schools⁸⁵

When the H1N1 outbreak first began in the United States, some affected communities closed schools when students were found to be infected. Legal authority to close schools rests with state or local officials and is highly variable among the states. A CDC-requested study found that school closure is legally possible in most jurisdictions during both routine and emergency situations.⁸⁶ The study also indicated that state authority for closure may be vested at various levels of government and in different departments, generally the state or local education agencies or state or local departments of health.

When the H1N1 pandemic first emerged in the spring, CDC, in consultation with the U.S. Department of Education, issued guidance with respect to school closures (based on earlier guidance from 2007), recommending that “affected communities with laboratory-confirmed cases of influenza A H1N1 consider adopting school dismissal and childcare closure measures, including closing for up to 14 days depending on the extent and severity of illness.”⁸⁷ School closures are challenging for all parties involved. Among other things, parents must find alternate arrangements for care of their children, educators must adopt alternate means of delivering their services, and children’s education may be compromised. On May 5, CDC officials reissued their guidance regarding school closures, recommending against closures based on individual cases of

⁸³ State assessment report, p. 43.

⁸⁴ See for example Rebecca Ruiz, “Behind The H1N1 Vaccine Shortage,” *Forbes*, October 30, 2009, and accompanying chart, “States With the Most and Least H1N1 Vaccine per 1,000 Residents,” updated periodically.

⁸⁵ For more information, see “School Closures” in CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones, and CDC, “Guidance for Child Care Programs, Schools, Colleges and Universities,” <http://www.cdc.gov/h1n1flu/guidance/>.

⁸⁶ James G. Hodge, Jr., Dhruvajyoti Bhattacharya, and Jennifer Gray, “Legal Preparedness for School Closures in Response to Pandemic Influenza and Other Emergencies,” <http://www.pandemicflu.gov/plan/school/schoolclosures.pdf>.

⁸⁷ CDC, “Change in CDC’s School and Childcare Closure Guidance,” press release, May 5, 2009, <http://www.cdc.gov/media/>. See, also, U.S. Department of Education, “H1N1 Flu Information,” <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/index.html>.

H1N1 flu. It recommended instead that emphasis be placed on keeping sick students and employees home, and that closings be considered if absenteeism was substantial.⁸⁸

As with CDC guidance in general, recommendations regarding school closure are intended to be weighed by local officials in light of local circumstances. In addition to uncertainty about the outbreak's initial severity, there may also have been uncertainty among state and local officials about decision-making protocols. In an assessment of state pandemic flu preparedness conducted by HHS and DHS in 2007 through 2008, planning for student dismissal and school closure was found to be a weakness among the states. More than half of them were graded as having either "many major gaps" or "inadequate preparedness" for this planning task.⁸⁹

Outbreaks in schools largely subsided over the summer. Transmission of the H1N1 virus re-emerged in a number of elementary and secondary schools and in colleges and universities as students returned for the fall. The American College Health Association (ACHA) began tracking voluntary reports of pandemic flu activity at colleges and universities.⁹⁰ For the week ending November 6, ACHA saw sustained high levels of nationwide reporting of influenza-like illnesses. Reporting was on the decline in many states, however.

Congressional Hearings

Congressional committees in both chambers have convened hearings to assess the emergence of the new strain of H1N1 influenza. Hearings are listed in **Table 2**.

Table 2. Congressional Hearings on the 2009 Influenza Pandemic

Date	Committee (/ Subcommittee)	Topic
SENATE		
Apr. 28, 2009	Appropriations / Labor, HHS, Education, and Related Agencies	The Public Health Response to the Swine Flu Epidemic
Apr. 29, 2009	Health, Education, Labor, and Pensions (HELP)	The Swine Flu Epidemic: The Public Health and Medical Response
Apr. 29, 2009	Homeland Security and Governmental Affairs Committee (HSGAC)	Swine Flu: Coordinating the Federal Response
May 7, 2009	Appropriations / Agriculture, Rural Development, and FDA	Hearing to Discuss the 2009 H1N1 Virus
June 3, 2009	HSGAC / State, Local and Private Sector Preparedness and Integration	Pandemic Flu: Closing the Gaps
June 16, 2009	HSGAC / Oversight of Government Management, the Federal Workforce and District of Columbia	Pandemic Flu Preparedness and the Federal Workforce
Sept. 21, 2009	HSGAC	H1N1 Flu: Protecting Our Community ^a

⁸⁸ CDC, "Update on School (K–12) and Child Care Programs: Interim CDC Guidance in Response to Human Infections with the Novel Influenza A (H1N1) Virus," May 5, 2009 (continually updated), http://www.cdc.gov/h1n1flu/K12_dismissal.htm.

⁸⁹ HHS and DHS, *Assessment of States' Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council*, "Operating Objective B.4—Enhance State Plans to Enable Community Mitigation through Student Dismissal and School Closure," January 2009, pp. 25–26, http://www.pandemicflu.gov/plan/states/state_assessment.html.

⁹⁰ American College Health Association, "Pandemic Influenza Surveillance: Influenza Like Illness (ILI) in Colleges and Universities," http://www.acha.org/ILI_Surveillance.cfm.

Date	Committee (/ Subcommittee)	Topic
Oct. 21, 2009	HSGAC	H1N1 Flu: Monitoring the Nation's Response
Nov. 10, 2009	HELP / Children and Families	The Cost of Being Sick: H1N1 and Paid Sick Days
Nov. 17, 2009	HSGAC	H1N1 Flu: Getting the Vaccine to Where It Is Needed Most
HOUSE		
Apr. 30, 2009	Energy and Commerce / Health	Swine Flu Outbreak and the U.S. Federal Response
May 6, 2009	Foreign Affairs / Africa and Global Health	Global Health Emergencies Hit Home: The Swine Flu Outbreak
May 7, 2009	Education and Labor	Ensuring Preparedness Against the Flu Virus at School and Work
May 14, 2009	Oversight and Government Reform / Federal Workforce, Postal Service, and the District of Columbia	Protecting the Protectors: An Assessment of Front-Line Federal Workers in Response to the H1N1 Flu
May 20, 2009	Oversight and Government Reform	State and Local Pandemic Preparedness
July 29, 2009	Homeland Security	Beyond Readiness: An Examination of the Current Status and Future Outlook of the National Response to Pandemic Influenza
Sept. 9, 2009	Small Business	The Challenges of the 2009-H1N1 Influenza and its Potential Impact on Small Businesses and Healthcare Providers
Sept. 15, 2009	Energy and Commerce	Preparing for the 2009 Pandemic Flu
Sept. 29, 2009	Oversight and Government Reform	The Administration's Flu Vaccine Program: Health, Safety, and Distribution
Oct. 27, 2009	Homeland Security / Subcommittee on Emerging Threats, Cybersecurity and Science, and Technology	Real-Time Assessment of the Federal Response to Pandemic Influenza
Nov. 17, 2009	Education and Labor	Protecting Employees, Employers and the Public: H1N1 and Sick Leave Policies
Nov. 18, 2009	Energy and Commerce / joint Health, Oversight and Investigations	H1N1 Preparedness: An Overview of Vaccine Production and Distribution

Source: Compiled by Congressional Research Service.

Notes: Hearings were held in Washington, DC unless otherwise noted. A Member briefing was held by the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies on November 4, 2009, with panelists from HHS, and from state and local health agencies.

a. Field hearing in Hartford, CT.

Appropriations and Funding

Public Health Emergency Funding Mechanisms

The Secretary of HHS does not have a dedicated source of funds to support the response to public health emergencies such as the current flu pandemic. Funds available to HHS from prior-year appropriations for pandemic flu could have supported vaccine development and modest

procurements, but would not have been adequate for procurements and related activities sufficient to support a mass-vaccination campaign. GAO has noted that the *National Strategy for Pandemic Influenza: Implementation Plan* (2006), which lays out 324 action items for federal agencies to prepare for and respond to a flu pandemic, contains no discussion of the possible costs of these actions, or how they would be financed.⁹¹

Upon the determination of a public health emergency pursuant to Section 319 of the Public Health Service Act, the Secretary of HHS may access a no-year Public Health Emergency Fund. Such a determination was made with respect to the H1N1 flu outbreak on April 26. (See the earlier section “Determination of a Public Health Emergency.”)⁹² The fund has not received a recent appropriation and does not have a balance, however, so the Secretary is not currently able to use this funding mechanism for the pandemic response.

There has not been a Stafford Act declaration for the current flu pandemic, so disaster relief funds administered by the Federal Emergency Management Agency (FEMA) are not available for response efforts. Many relevant activities may not be eligible for Stafford funds, even if they were available.⁹³ (See the earlier section, “Applicability of the Stafford Act.”)

The Secretary has authority to use a Covered Countermeasure Process Fund to compensate individuals for harm that results from their use of medical countermeasures, as identified in a declaration issued by the HHS Secretary.⁹⁴ A declaration was issued for the use of the antiviral drugs Tamiflu and Relenza for a possible pandemic flu virus in October 2008.⁹⁵ As noted earlier, a declaration was issued for the use of H1N1 pandemic vaccines in June, 2009.⁹⁶ Compensation could be provided for serious physical injuries or deaths resulting from the use of these products in this situation, including for unapproved uses pursuant to an Emergency Use Authorization. (See “FDA: Emergency Use Authorizations.”) In FY2009 emergency supplemental funding for pandemic preparedness (P.L. 111-32), Congress authorized the use of an unspecified amount of the appropriation for the Covered Countermeasure Process Fund, and President Obama has sought to use contingent funds provided under the law for this purpose.⁹⁷

⁹¹ U.S. Government Accountability Office, *Influenza Pandemic: Continued Focus on the Nation’s Planning and Preparedness Efforts Remains Essential*, GAO-09-760T, June 3, 2009, pp. 10-11, <http://www.gao.gov>. See also Homeland Security Council, *National Strategy for Pandemic Influenza: Implementation Plan*, May 2006, <http://www.pandemicflu.gov/plan/federal/pandemic-influenza-implementation.pdf>.

⁹² For more information, see “Federal Funding to Support an ESF-8 Response,” in CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister.

⁹³ See “Federal Statutory Authorities for Disaster Response” and “Federal Funding to Support an ESF-8 Response,” in CRS Report RL33579, *The Public Health and Medical Response to Disasters: Federal Authority and Funding*, by Sarah A. Lister. See also CRS Report RL34724, *Would an Influenza Pandemic Qualify as a Major Disaster Under the Stafford Act?*, by Edward C. Liu.

⁹⁴ CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation*, by Henry Cohen and Vanessa K. Burrows. The compensation program is administered by the Health Resources and Services Administration (HRSA) in HHS.

⁹⁵ HHS, “Declaration Under the Public Readiness and Emergency Preparedness Act” (notice regarding use of Tamiflu and Relenza), 73 *Federal Register* 61861-61864, October 17, 2008.

⁹⁶ HHS, Office of the Secretary, “Pandemic Influenza Vaccines—Amendment,” 74 *Federal Register* 30294-30297, June 25, 2009.

⁹⁷ H.Rept. 111-151, to accompany H.R. 2346, making supplemental appropriations for FY2009, June 12, 2009, pp. 114-115.

Emergency Supplemental Appropriations for FY2009⁹⁸

In June, the Obama Administration requested \$2 billion in FY2009 emergency supplemental appropriations for response to the H1N1 threat, and authority to transfer additional amounts, totaling almost \$7 billion, from existing HHS accounts. The Supplemental Appropriations Act, FY2009 (P.L. 111-32), signed on June 24, 2009, provided \$1.9 billion in supplemental appropriations immediately,⁹⁹ and an additional \$5.8 billion contingent upon a presidential request documenting the need for additional funds. Amounts provided are as follows:¹⁰⁰

- \$1.85 billion to the HHS Public Health and Social Services Emergency Fund (PHSSEF), available until expended, including not less than \$200 million to CDC for several specified activities, and not less than \$350 million for state and local public health response capacity.
- Of the \$1.3 billion to HHS not specifically designated, the Secretary may transfer funds to other HHS accounts and to other federal agencies. Also, these funds may be used for purchases for the Strategic National Stockpile (SNS), for construction or renovation of privately owned vaccine production facilities, and for the Covered Countermeasure Process Fund (CCPF).
- An additional contingent emergency appropriation of \$5.8 billion to the HHS PHSSEF would become available for obligation 15 days after the President provided a detailed written request to Congress to obligate specific amounts for specific purposes, and only if needed to address the emergency. If such requirements were met, funds could generally be made available and transferred as above, including for purchases for the SNS and the CCPF. However, contingent funds could not be used for construction or renovation of privately owned vaccine production facilities.
- \$50 million to the President for the Global Health and Child Survival account to support global efforts to control the spread of the outbreak.
- The conference report provided that if WHO were to announce that the current outbreak had progressed to a flu pandemic (i.e., Phase 6),¹⁰¹ and upon the President's determination and notification to Congress, available funds in four accounts from prior appropriations acts for the Department of State, Foreign Operations, and Related Programs—Global Health and Child Survival; Development Assistance; Economic Support Fund; and Millennium Challenge Corporation—may be used for pandemic response activities.

President Obama has twice requested portions of the contingent funding, totaling \$4.541 billion, leaving a balance of \$1.259 billion that the President may request at a later date. On July 16, the President requested \$1.825 billion of the contingent appropriation, to be used for procurement of vaccine adjuvant, immunization campaign planning, FDA regulatory activities, and funding for the CCPF.¹⁰² On September 2, the President requested an additional \$2.716 billion of the

⁹⁸ Information in this section is tracked in greater detail in CRS Report R40531, *FY2009 Spring Supplemental Appropriations for Overseas Contingency Operations*, coordinated by Stephen Daggett and Susan B. Epstein.

⁹⁹ Amount includes \$1.85 billion to HHS for the Public Health and Social Services Emergency Fund and \$50 million to the President for the Global Health and Child Survival account.

¹⁰⁰ H.Rept. 111-151, pp. 27-28, 34-35, 110, 114-116, 125-126, and 142.

¹⁰¹ WHO declared the situation to be a flu pandemic, Phase 6, on June 11.

¹⁰² The White House, Text of a Letter from the President to the Speaker of the House of Representatives, July 16, 2009,

contingent appropriation, to be used for the Departments of Agriculture, Defense, HHS, State, and Veterans Affairs to support the procurement of vaccine product and supplies, antiviral medications, preparations for a vaccination campaign, and agency preparedness activities.¹⁰³

Prior Funding for Pandemic Flu Preparedness

In the fall of 2005, in the aftermath of Hurricane Katrina, and as H5N1 avian flu was spreading across several continents, Congress provided \$6.1 billion in FY2006 supplemental appropriations for pandemic planning across several federal departments and agencies.¹⁰⁴ Since then, annual funding has been provided to CDC, FDA, and for other activities in HHS to continue work on vaccine development, stockpiling of countermeasures, and assistance to states. In total, from FY2004 through FY2009, HHS has received almost \$13.4 billion for pandemic flu preparedness.¹⁰⁵ (See **Table 3**.) The U.S. Departments of Agriculture and the Interior have also received annual funding to monitor avian flu in domestic poultry and wild birds, respectively. The U.S. Agency for International Development (USAID) has received funds to assist other countries in managing avian flu transmission to humans, and preparing for a possible pandemic.¹⁰⁶

In addition to amounts it specifically appropriates, Congress is also interested in how agencies budget for influenza within their existing activities. However, defining such amounts is difficult, for two reasons. First, for many years, domestic public health capacity for infectious disease control has moved away from “categorical” funding and programs (i.e., one disease at a time), and toward the development of flexible capacity that can adapt to new, unanticipated threats. These flexible surveillance systems, laboratory networks, communications platforms, and other capabilities can pivot rapidly to address new threats. But because pandemic planning efforts are tightly woven into the fabric of these flexible capabilities, it is not easy to tease out threads that describe the nation’s investment solely for pandemic flu preparedness. Attempt to do so requires making judgments about what is “in” and “out” of scope that are somewhat arbitrary.

Second, for similar reasons, it can be difficult to tease apart investments made for pandemic flu, versus seasonal flu, versus avian or swine flu, versus investments in drug and vaccine development in general. Because different agencies use different methods and assumptions to account for their influenza spending, these amounts are not necessarily comparable between agencies, and caution is advised in adding such amounts together as if they were comparable.

HHS has tracked its pandemic influenza funding for the past several fiscal years, using comparable criteria from year to year. These amounts are presented in the department’s annual budget requests, in sections designated for pandemic influenza, and are presented in **Table 3**.

http://www.whitehouse.gov/omb/budget_amendments/.

¹⁰³ The White House, Text of a Letter from the President to the Speaker of the House of Representatives, September 2, 2009, http://www.whitehouse.gov/omb/budget_amendments/.

¹⁰⁴ CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, by Sarah A. Lister.

¹⁰⁵ This amount includes funds made available through contingent transfer authority as provided in FY2009 supplemental appropriations, discussed in the previous section of this report. This amount excludes funds provided to other federal departments or agencies.

¹⁰⁶ Information can be found in CRS Reports on the applicable appropriations bills, at <http://crs.gov/Pages/CLIs.aspx?CLIID=73>, and: CRS Report R40239, *Centers for Disease Control and Prevention Global Health Programs: FY2001-FY2010*, by Tiaji Salaam-Blyther.

Table 3. HHS Funding for Pandemic Influenza, FY2004-FY2010

(dollars in millions, rounded)

Agency/Activity	FY2004	FY2005	FY2006 ^a	FY2007	FY2008	FY2009 regular ^b	FY2009 supp. ^c	FY2010 req.
OS and/or PHSSEF	50	99	5,152	0	75	585	6,391	354
CDC	0	0	400	70	155	156	0	156
FDA	0	0	20	33	35	39	0	39
NIH	0	0	18	35	34	35	0	35
TOTAL, Program Level	50	99	5,590^d	138	299	815	6,391^c	584

Source: Compiled by Congressional Research Service from HHS annual “Budget in Brief” documents at <http://www.hhs.gov/asrt/ob/docbudget/>, unless otherwise noted below.

Notes: OS is Office of the HHS Secretary. PHSSEF is Public Health and Social Services Emergency Fund, an account administered by the Secretary, which Congress has typically used to provide one-time funding for non-routine activities. NIH is the National Institutes of Health.

- a. Appropriated in P.L. 109-148, the Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006, and P.L. 109-234, the Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Hurricane Recovery, 2006. Funds are available until expended.
- b. Appropriated in P.L. 111-8, the Omnibus Appropriations Act, 2009. Pandemic flu funding was not included in P.L. 111-5, the American Recovery and Reinvestment Act of 2009 (ARRA).
- c. Appropriated in P.L. 111-32, the Supplemental Appropriations Act, 2009. The Act provided the Secretary of HHS with \$1.850 billion initially and an additional \$5.8 billion contingent upon presidential request and demonstration of need. For more information, see CRS Report R40531, *FY2009 Spring Supplemental Appropriations for Overseas Contingency Operations*, coordinated by Stephen Daggett and Susan B. Epstein. Amount includes the initial amount (i.e., \$1.850 billion) plus \$4.541 billion in contingent appropriations. (President Obama requested \$1.825 billion in contingent appropriations on July 16, and an additional \$2.716 billion on September 2. See footnote 102 and footnote 103.)
- d. Total does not include \$30 million in supplemental funding to HHS that was transferred to the U.S. Agency for International Development (USAID).

U.S. Pandemic Influenza Preparedness Documents

In the George W. Bush Administration, pandemic flu preparedness efforts were coordinated by the Homeland Security Council.¹⁰⁷ Numerous federal and other documents that are specific to preparedness and response for a flu pandemic have been published. Selected documents are listed below. These plans are intended to address a pandemic caused by any so-designated flu strain, but they were written when there was significant global concern about H5N1 avian flu. To date, that flu strain has behaved quite differently from the H1N1 pandemic strain. In particular, the H5N1 strain has not shown the ability to transmit efficiently from person to person, but human

¹⁰⁷ Incident preparedness and response are different functions. At each level of government, they involve different leadership roles, legal authorities, organizational structures, and funding mechanisms. Generally, during an incident, certain conditions must be met before a jurisdiction can implement response activities, or access funds reserved for that purpose. With respect to the current H1N1 pandemic, the U.S. federal government has commenced pandemic flu response activities, under the overall coordination of the Secretary of Homeland Security.

infections that result directly from contact with infected poultry have generally been very severe, and there has been a high fatality rate.¹⁰⁸

Unless otherwise noted, the U.S. pandemic flu plans below can be found on a government-wide pandemic flu website managed by HHS.¹⁰⁹

- The *National Strategy for Pandemic Influenza*, November 2005, published by the Homeland Security Council, outlines general responsibilities of individuals, industry, state and local governments, and the federal government in preparing for and responding to a pandemic.
- *National Strategy for Pandemic Influenza, Implementation Plan*, May 2006, published by the Homeland Security Council, assigns more than 300 preparedness and response tasks to departments and agencies across the federal government; includes measures of progress and timelines for implementation; provides initial guidance for state, local, and tribal entities, businesses, schools and universities, communities, and non-governmental organizations on the development of institutional plans; provides initial preparedness guidance for individuals and families. One- and two-year implementation status reports have also been published.
- The *HHS Pandemic Influenza Plan*, November 2005, provides guidance to national, state and local policy makers and health departments, outlining key roles and responsibilities during a pandemic and specifying preparedness needs and opportunities. This plan emphasizes specific preparedness efforts in the public health and health care sectors.
- The *HHS Pandemic Influenza Implementation Plan, Part I*, November 2006, discusses department-wide activities: disease surveillance; public health interventions; medical response; vaccines, antiviral drugs, diagnostic tests, and personal protective equipment (PPE); communications; and state and local preparedness.
- *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States—Early Targeted Layered use of Non-Pharmaceutical Interventions*, February 2007, published by CDC, guidance for “social distancing” strategies to reduce contact between people, with respect to: closing schools; canceling public gatherings; planning for liberal work leave policies; teleworking strategies; voluntary isolation of cases; and voluntary quarantine of household contacts.
- *Department of Defense Implementation Plan for Pandemic Influenza*, August 2006, provides policy and guidance for the following priorities: (1) force health protection and readiness; (2) the continuity of essential functions and services; (3) Defense support to civil authorities (i.e., federal, state, and local governments); (4) effective communications; and (5) support to international partners.
- *VA Pandemic Influenza Plan*, March 2006, provides policy and instructions for Department of Veterans Affairs (VA) in protecting its staff and the veterans it serves,

¹⁰⁸ For more information about H5N1 avian flu and related public health concerns, see WHO, *Avian influenza*, http://www.who.int/csr/disease/avian_influenza/en/index.html; WHO, *Confirmed Human Cases of Avian Influenza A(H5N1)*, http://www.who.int/csr/disease/avian_influenza/country/en/; and CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by Sarah A. Lister (archived).

¹⁰⁹ See <http://www.flu.gov/professional/federal/index.html>.

maintaining operations, cooperating with other organizations, and communicating with stakeholders.

- *Pandemic Influenza Preparedness, Response, and Recovery Guide for Critical Infrastructure and Key Resources*, published by DHS, September 2006, provides business planners with guidance to assure continuity during a pandemic for facilities comprising critical infrastructure sectors (e.g., energy and telecommunications) and key resources (e.g., dams and nuclear power plants).
- *State pandemic plans*: All states were required to develop and submit specific plans for pandemic flu preparedness, as a requirement of grants provided by HHS.¹¹⁰

Key Information Sources

CRS Reports and Experts

2009 H1N1 “Swine Flu”: **CRS Experts:** CRS Report R40845, *2009 H1N1 “Swine Flu”*: *CRS Experts*, by Sarah A. Lister.

Current CRS Reports on public health and emergency preparedness in general:

http://apps.crs.gov/cli/cli.aspx?PRDS_CLI_ITEM_ID=3276&from=3&fromId=13

Current CRS Reports on specific aspects of the pandemic influenza threat:

- CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.
- CRS Report RS21414, *Mandatory Vaccinations: Precedent and Current Laws*, by Kathleen S. Swendiman.
- CRS Report RL34724, *Would an Influenza Pandemic Qualify as a Major Disaster Under the Stafford Act?* by Edward C. Liu.
- CRS Report R40531, *FY2009 Spring Supplemental Appropriations for Overseas Contingency Operations*, coordinated by Stephen Daggett and Susan B. Epstein.
- CRS Report R40575, *Potential Farm Sector Effects of 2009 H1N1 “Swine Flu”*: *Questions and Answers*, by Renée Johnson.
- CRS Report R40588, *The 2009 Influenza Pandemic: U.S. Responses to Global Human Cases*, by Tiaji Salaam-Blyther.
- CRS Report R40619, *The Role of the Department of Defense During A Flu Pandemic*, by Lawrence Kapp and Don J. Jansen.
- CRS Report RL33609, *Quarantine and Isolation: Selected Legal Issues Relating to Employment*, by Nancy Lee Jones and Jon O. Shimabukuro.
- CRS Report RS21507, *Project BioShield: Purposes and Authorities*, by Frank Gottron.
- CRS Report R40570, *Immigration Policies and Issues on Health-Related Grounds for Exclusion*, by Chad C. Haddal and Ruth Ellen Wasem.

¹¹⁰ For more information, see HHS, *Assessment of States’ Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council*, January 2009, at <http://www.pandemicflu.gov/plan/states/index.html>, and CRS Report RL34190, *Pandemic Influenza: An Analysis of State Preparedness and Response Plans*, by Sarah A. Lister and Holly Stockdale.

- CRS Report RL32724, *Mexico-U.S. Relations: Issues for Congress*, by Clare Ribando Seelke, Mark P. Sullivan, and June S. Beittel.
- CRS Report RL33381, *The Americans with Disabilities Act (ADA): Allocation of Scarce Medical Resources During a Pandemic*, by Nancy Lee Jones.
- CRS Report RS22327, *Pandemic Flu and Medical Biodefense Countermeasure Liability Limitation*, by Henry Cohen and Vanessa K. Burrows.
- CRS Report RL31873, *Banking and Financial Infrastructure Continuity: Pandemic Flu, Terrorism, and Other Challenges*, by N. Eric Weiss.
- CRS Report RS22264, *Federal Employees: Human Resources Management Flexibilities in Emergency Situations*, by Barbara L. Schwemle.

Archived CRS Reports on the threat of pandemic influenza: These products generally discuss concerns about a possible human flu pandemic resulting from H5N1 avian influenza, and enhanced federal preparedness efforts during 2005 through 2007.

- CRS Report RL33145, *Pandemic Influenza: Domestic Preparedness Efforts*, by Sarah A. Lister.
- CRS Report RL33219, *U.S. and International Responses to the Global Spread of Avian Flu: Issues for Congress*, by Tiaji Salaam-Blyther.
- CRS Report RS22576, *Pandemic Influenza: Appropriations for Public Health Preparedness and Response*, by Sarah A. Lister.

World Health Organization (WHO) Information

- Information about the current H1N1 pandemic flu situation: <http://www.who.int/csr/disease/swineflu/en/index.html> (See also the **Appendix**.)
- Pandemic Influenza Preparedness and Response: A WHO Guidance Document, (April 2009): <http://www.who.int/csr/disease/influenza/pipguidance2009/en/index.html>
- Current phase of flu pandemic alert: http://www.who.int/csr/disease/avian_influenza/phase/en/index.html
- Pan American Health Organization (PAHO), a regional office of the WHO, H1N1 flu page: http://new.paho.org/hq/index.php?option=com_content&task=blogcategory&id=805&Itemid=569
- International Health Regulations (2005): http://www.who.int/topics/international_health_regulations/en/

U.S. Federal Government Information

- Government-wide information: <http://www.flu.gov/>
- DHS, “Department Response to H1N1 (Swine) Flu,” with links to information in other federal departments and agencies: <http://www.dhs.gov/xprepresp/programs/swine-flu.shtm>
- CDC, H1N1 (swine flu) page: <http://www.cdc.gov/h1n1flu/>
- CDC Public Health Law Program, 2009 H1N1 Flu Legal Preparedness, <http://www2a.cdc.gov/phlp/H1N1flu.asp>

- FDA, 2009 H1N1 (Swine) Flu Virus, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm150305.htm>
- Centers for Medicare and Medicaid Services (CMS), H1N1 information page, <http://www.cms.hhs.gov/H1N1/>
- U.S. Department of Education, H1N1 Flu Information, <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/index.html>
- U.S. Department of Agriculture (USDA), H1N1 Flu, http://www.usda.gov/wps/portal/?navid=USDA_H1N1
- USDA nutrition program policies for pandemic flu, <http://www.fns.usda.gov/disasters/pandemic/default.htm>
- Department of Defense Pandemic Influenza Watchboard: <http://fhp.osd.mil/aiWatchboard/>
- HHS Pandemic Planning Updates, addressing monitoring and surveillance, vaccines, antiviral medications, state and local preparedness, and communications, through January 2009: <http://www.flu.gov/professional/federal/index.html> (Note: much of this information is in the context of planning for the H5N1 avian flu threat.)

Additional Information

- Canada: Public Health Agency of Canada: http://www.phac-aspc.gc.ca/alert-alerte/swine_200904-eng.php; Canadian Food Inspection Agency: <http://www.inspection.gc.ca/english/animadise/mala/swigri/swigrie.shtml>
- Security and Prosperity Partnership of North America, *North American Plan for Avian and Pandemic Influenza*, August 2007, [http://www.spp-psp.gc.ca/eic/site/spp-psp.nsf/vwapj/pandemic-influenza.pdf/\\$FILE/pandemic-influenza.pdf](http://www.spp-psp.gc.ca/eic/site/spp-psp.nsf/vwapj/pandemic-influenza.pdf/$FILE/pandemic-influenza.pdf)
- Center for Infectious Disease Research and Policy (CIDRAP), at the University of Minnesota, frequent updates, including scientific and technical information, <http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/index.html>
- Public Health Law and Policy Program at the Sandra Day O'Connor College of Law, at Arizona State University, Global Legal Triage and the 2009 H1N1 Outbreak (including prior and existing declared emergencies at the federal and state levels), <http://www.law.asu.edu/?id=2036>

Appendix. Key Official Actions by WHO

Determination of Influenza Pandemic Phase

The World Health Organization is the coordinating authority for health within the United Nations system. It is responsible for providing leadership, guiding a research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends. WHO does not have enforcement powers.

An influenza pandemic occurs when a novel flu strain emerges and spreads across the globe, causing human illnesses. For that to happen, the virus must have the following features: it must be genetically novel so that there is a lack of preexisting immunity; it must be pathogenic (i.e., capable of causing illness in humans); and it must be easily transmitted from person to person.

WHO, in consultation with experts in member countries, monitors the spread of influenza among human populations, and has developed a scale to monitor pandemic risk. It consists of five “pre-pandemic” phases with increasing incidence of animal and then human illness and transmission, and a sixth phase that represents a full-blown human pandemic, with sustained viral transmission and outbreaks in most or all regions of the world. Historically, flu pandemics have occurred in multiple waves before subsiding. **Table A-1** describes the phases of a flu pandemic, as defined by WHO.

As a result of the rapid spread of the new flu strain, WHO raised the pandemic alert level from Phase 3, where it had been for several years because of the threat of H5N1 avian flu, to Phase 4 on April 27, and then to Phase 5 on April 29.¹¹¹ Phase 3 meant that a novel flu strain was causing sporadic small clusters of human illness, but was not sufficiently transmissible to sustain community-level outbreaks. Phase 4, by contrast, signaled that human-to-human transmission of the new H1N1 virus was sufficient to sustain community-level outbreaks. According to WHO, raising the alert level to Phase 5 meant that there was sustained community-level transmission in two or more countries within one WHO region, and that a pandemic could be imminent.

On June 11, WHO raised the level to Phase 6, declaring that an influenza pandemic, caused by the new H1N1 strain, was underway. According to WHO Director General Dr. Margaret Chan:

Spread in several countries can no longer be traced to clearly-defined chains of human-to-human transmission. Further spread is considered inevitable.... The world is now at the start of the 2009 influenza pandemic. We are in the earliest days of the pandemic. The virus is spreading under a close and careful watch. No previous pandemic has been detected so early or watched so closely, in real-time, right at the very beginning. The world can now reap the benefits of investments, over the last five years, in pandemic preparedness.¹¹²

Table A-1. WHO Influenza Pandemic Phases
(current alert level is highlighted)

Phase	Description
Phase I	No animal influenza virus circulating among animals has been reported to cause infection in humans.

¹¹¹ WHO, “Pandemic (H1N1) 2009,” <http://www.who.int/csr/disease/swineflu/en/index.html>.

¹¹² WHO, “World Now at the Start of 2009 Influenza Pandemic” (Statement of Dr. Margaret Chan), press release, June 12, 2009, <http://www.who.int/csr/disease/swineflu/en/index.html>.

Phase	Description
Phase 2	An animal influenza virus circulating in domesticated or wild animals is known to have caused infection in humans and is therefore considered a specific potential pandemic threat.
Phase 3	An animal or human-animal influenza reassortant ^a virus has caused sporadic cases of small clusters of disease in people, but has not resulted in human-to-human transmission sufficient to sustain community-level outbreaks.
Phase 4	Human-to-human transmission of an animal or human-animal influenza reassortant ^a virus able to sustain community-level outbreaks has been verified.
Phase 5	The same identified virus has caused sustained community-level outbreaks in two or more countries in one WHO region. ^b
Phase 6	An influenza pandemic. In addition to the criteria defined in Phase 5, the same virus has caused sustained community-level outbreaks in at least one other country in another WHO region. ^b
Post-peak Period	Levels of pandemic influenza in most countries with adequate surveillance have dropped below peak levels.
Possible New Wave	Level of pandemic influenza activity in most countries with adequate surveillance rising again.
Post-pandemic Period	Levels of influenza activity have returned to the levels seen for seasonal influenza in most countries with adequate surveillance.

Source: Adapted by CRS from WHO, *Pandemic Influenza Preparedness and Response: A WHO Guidance Document*, April 2009, Table 1, p. 13, <http://www.who.int/csr/disease/influenza/pipguidance2009/en/index.html>.

- a. A reassortant virus results from a genetic reassortment process in which genes from animal and human influenza viruses mix together to create a new strain.
- b. WHO governs through six regional offices that do not strictly correspond with the world's continents. The WHO regions are the African Region; the Region of the Americas; the South-East Asia Region; the European Region; the Eastern Mediterranean Region; and the Western Pacific Region. See "WHO—Its People and Offices," <http://www.who.int/about/structure/en/index.html>.

For several years, WHO urged governments, corporations, and other interests to develop pandemic influenza preparedness and response plans. Generally these plans are staged according to WHO pandemic phases. WHO has noted that under the current definitions, pandemic phases do not reflect the severity of illness, but rather the global extent of sustained community-level outbreaks. Some members of the public, however, had come to think of any flu pandemic as a catastrophic incident on the scale of the one that occurred in 1918, or that many feared could result from the deadly H5N1 avian flu if it became transmissible among humans. Some argued that the definition of a pandemic should be rewritten to take severity into account, and that a Phase 6 pandemic designation for the H1N1 flu situation would trigger over-reactions that were more disruptive than the disease.¹¹³

International Health Regulations

In 2005, the World Health Assembly adopted revised International Health Regulations (IHR), revising the roles and responsibilities of WHO and member states in the protection of international public health. The IHR(2005) require signatory nations (which include the United States) to notify WHO of all events that may constitute a "Public Health Emergency of International Concern," and to provide relevant information. The IHR(2005) also include

¹¹³ See, for example, Robert Roos, "WHO Drawing Closer to Declaring a Pandemic," *CIDRAP News* (Center for Infectious Disease Research and Policy), June 2, 2009, <http://www.cidrap.umn.edu/cidrap/content/influenza/swineflu/index.html>.

provisions regarding designated national points of contact, definitions of core public health capacities, disease control measures such as quarantine and border controls (which are to be no more restrictive than necessary to achieve the desired level of health protection) and others.¹¹⁴ On April 25, 2009, upon the advice of the Emergency Committee called under the rules of the IHR(2005), the WHO Director-General declared the H1N1 flu outbreak a Public Health Emergency of International Concern, thereby calling upon signatories to provide timely and transparent notification of events to WHO, to collaborate in disease reporting and control, and to adopt effective risk communication strategies to reduce the potential for international disease spread and the unilateral imposition of trade or travel restrictions by other countries.¹¹⁵

Travel Guidance

A number of governments have instituted enhanced passenger screening practices at their borders, and policymakers have debated more extensive prohibitions against the entry of travelers from countries or areas affected by the outbreak. The WHO has consistently advised against movement restrictions as a means to control influenza, citing a lack of evidence of their effectiveness, coupled with their potentially harmful effects on public confidence, local economies, and trade.¹¹⁶

Food Safety Guidance¹¹⁷

WHO has published a joint statement with Food and Agriculture Organization of the United Nations (FAO), the World Organization for Animal Health (known by its French acronym, OIE), and the World Trade Organization (WTO), saying:

In light of the spread of influenza A(H1N1), and the rising concerns about the possibility of this virus being found in pigs and the safety of pork and pork products, we stress that pork and pork products, handled in accordance with good hygienic practices recommended by the WHO, FAO, Codex Alimentarius Commission and the OIE, will not be a source of infection.

To date there is no evidence that the virus is transmitted by food. There is currently therefore no justification in the OIE Terrestrial Animal Health Standards Code for the imposition of trade measures on the importation of pigs or their products.¹¹⁸

¹¹⁴ For more information, see CRS Report R40560, *The 2009 Influenza Pandemic: Selected Legal Issues*, coordinated by Kathleen S. Swendiman and Nancy Lee Jones.

¹¹⁵ WHO, *International Health Regulations*, <http://www.who.int/ihr/en/>. See, also, Rebecca Katz, "Use of Revised International Health Regulations during Influenza A (H1N1) Epidemic," *Emerging Infectious Diseases*, vol. 15, no. 8 (August 2009), <http://www.cdc.gov/eid/content/15/8/1165.htm>.

¹¹⁶ WHO, *No Rationale for Travel Restrictions*, May 1, 2009, http://www.who.int/csr/disease/swineflu/guidance/public_health/travel_advice/en/index.html.

¹¹⁷ For more information, see CRS Report R40575, *Potential Farm Sector Effects of 2009 H1N1 "Swine Flu": Questions and Answers*, by Renée Johnson.

¹¹⁸ *Joint FAO, OIE, WHO and WTO Statement on A(H1N1) virus*, May 2, 2009, http://www.wto.org/english/news_e/news09_e/jt_stat_02may09_e.htm.

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Acknowledgments

Legislative Attorneys Kathleen Swendiman, Edward Liu, and Nancy Jones, and Specialists Keith Bea and Frank Gottron, assisted with information in this report regarding federal emergency management authorities, including Figure 1.

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